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NON-INVASIVE EXTENDING PROSTHESIS

JAYANTILAL (JAY) MOHANLAL MESWANIA

PhD THESIS

JUNE 2006

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TABLE OF CONTENTS

ABSTRACT

Abstract

Most sarcomas of the bone occur in patients of a relatively young age including skeletally immature patients. Approximately 50 child sarcomas are treated with limb salvage surgery per year in the United Kingdom. These children need an extendible implant that can be lengthened periodically to keep pace with the growth in the opposite limb. Surgically, invasive devices have been used for the past thirty years with intrinsic problems of infection and long-term recurrent trauma to the patient. To eliminate problems associated with the invasive device I have attempted to develop a non-invasive extendible prosthesis by utilising a magnetically coupled drive.

The aims of this study were to ascertain the clinical requirements of an electro-mechanical design, evaluate the performance of the proposed design, validate the design by *in vitro* tests and conclude its effectiveness by conducting an *in vivo* clinical trial. The final aim was to develop a similar concept for the distraction of juvenile spinal scoliosis.

The drive technology used in this device is an induction motor with a gear driven telescoping prosthesis. In very young patients the potential loss of growth in the resected bone usually exceeds the amount of extension that could be built into the prosthesis. Therefore, maximisation of the growth potential was the prime objective of the prospective design. A previously designed two-stage epicyclic gearbox was tested and improvements were made to provide a load carrying capacity identified by *in vivo* measurements conducted in over 30 patients. In this design the motor configuration is in two parts: a rotor which fits inside the prosthesis and a stator which is an external device used to extend the prosthesis remotely. A compact external drive was developed with focused magnetic flux which required no cooling and operated on a single-phase power supply. The effect of the magnetic rotor on the diagnostic imaging was tested and the findings are reported in this thesis. A number of patients were treated with this new device and the clinical outcome is presented. A different version of the device for use with a spinal rod system was developed for the treatment of juvenile scoliosis.

ACKNOWLEDGEMENTS

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My special thanks go to Mrs Annie Bartram for her help in the preparation of this thesis and putting up with my constant interruptions.

Last, but not the least, my family for their support and understanding.

LIST OF FIGURES

List of figures

LIST OF TABLES

List of tables

CHAPTER 1

INTRODUCTION

1.1 Background

Bone tumours in people occur in various forms throughout all ages. However, most sarcomas of the bone occur in patients of a relatively young age including skeletally immature patients (Blackwell *et al.*, 2005). Usually these tumours fall into one of two categories: malignant tumours which are very aggressive (Campbell *et al.*, 1977) and if left untreated can lead to fatality; benign tumours which are non-malignant and in most cases patients can live for many years without any further medical treatment. Table 1.1 shows various forms of tumours and the number of cases that were treated using endoprosthetic replacements at the Centre for Biomedical Engineering, Institute of Orthopaedics & Musculo-Skeletal Science, Stanmore to date. The most commonly treated conditions are osteosarcoma (40.5%), chondrosarcoma (17.5%), metastasis (12.3%), osteoclastoma (6.9%), malignant fibrosis histosarcoma (5.8%) and Ewing's sarcoma (4.5%). The remaining cases (12.5%) account for less frequently occurring tumours. Although, benign tumours are not always treated, the lack of structural integrity of the diseased bone may necessitate surgical intervention.

The skeleton has evolved to provide rigidity to the body by reinforcing the soft tissues in a way which does not interfere with the functions of other organs. The skeletal structure has also evolved into a collection of smaller segments integrated with muscular tissues to allow various forms of controlled movements between the segments. For the joints to function efficiently nature has evolved optimised shapes in compliance with the mechanics of the motion, forming lubricated bearing surfaces. Nature has also optimised the bone structure and composition and has programmed a regenerative mechanism which maintains bone strength throughout life and is able to respond to changing lifestyle. The body controls this regenerative process by monitoring the strains in the bone. Bone prefers strain levels within a range called osteogenic strains which, if reduced, induces bone resorption to bring the strain level back up, whilst if increased bone growth is produced to reduce the strain (Rubin *et al.*, 1984; Storey *et al.*, 1986). The actual

Type of tumour	% of the total	No of cases
Osteosarcoma	40.5	312
Chondrosarcoma	17.5	135
Metastasis	12.3	95
Osteoclastoma	6.9	53
Malignant fibrosis histosarcoma	5.8	45
Ewing's sarcoma	4.5	35
Spindle cell sarcoma	2.3	18
Parosteal sarcoma	1.8	14
Chondroblastoma	1.3	10
Lymphoma	1.3	10
Leiomyosarcoma	0.9	7
Plasmacytoma	0.6	5
Myeloma	0.4	3
Benign fibrosis histosarcoma	0.3	2
Liposarcoma	0.3	2
Osteochondroma	0.3	2
Osteomyelitis	0.3	2
Sarcoma low grade	0.3	2
Anaplasia carcinoma	0.1	1
Aneurismal bone cyst	0.1	1
Benign lesion	0.1	1
Charcot's joint	0.1	1
Fibrosarcoma	0.1	1
Fibrous dysplasia	0.1	1
Haemangioendo'ma	0.1	1
Haemangio-pericytoma	0.1	1
Lyposarcoma	0.1	1
Lytic lesion	0.1	1
Malignant lesion	0.1	1
Neurofibrosarcoma	0.1	1
Osteoarthritis	0.1	1
Osteoblastoma	0.1	1
Paget's disease	0.1	1
Peripheral nerve tumour	0.1	1
Rad Ind Sarcoma	0.1	1
Rhabdomyosarcoma	0.1	1
Synovial sarcoma	0.1	1
	100%	Total = 771

Table 1.1 Tumour cases treated to date at this Institution.

strain level at which the bone response occurs is also linked with the frequency and mode of load cycles (Visconti *et al.*, 2004), making a very complicated closed loop control for the regenerative system. This mechanism is evident as remodelling seen in the bone in response to daily loading cycles (Lanyon, 1996) and as a reaction to orthopaedic implants (Blunn *et al.*, 1991). This regenerative process is ongoing in the body and perhaps ironically it is this process, at the cellular level, that gives the opportunity for a rogue cell to develop and multiply into an undesirable cancerous form. Naturally, the regenerative process is most active in young patients and hence more cancers are seen in juveniles than in the older generation.

Although formation of a rogue cell can occur almost anywhere in the body, they tend to proliferate at certain sites. Depending on the location and patient age, the rogue cell develops into a particular type of disease. Therefore there is a pattern in the way the disease develops, where it develops and a particular age at which it proliferates. The actual shape of the growth depends on the type of cancer and the period of its existence. The biology behind the cancer growth is outside the scope of this study, but it is important to appreciate how the cancer grows and affects the remaining normal tissues around it.

To provide an effective treatment for bone cancers in children, it is important to understand in a generalised sense the way in which the juvenile bone grows. Bone growth occurs through the epiphysis, usually sited near the joints, and through enlargement of the cross section of the bone whereby both of these growths require synchronisation so that the overall proportions are maintained. As the epiphysial growth is on the diaphysial side the growth plate always remains close to the joint. Furthermore, bone in between the epiphysis and the joint also forms and changes into an anatomical joint shape as the child grows, during which time the bone tissues go through a density change. Personal experience gained by me over the past thirty years in custom-made implant design suggests that in a very young child, the bone near the joint is almost indistinguishable from the surrounding soft tissues

when using normal imaging, making it very difficult to define the bone boundary for replication.

In the early days, cancer treatment resulted in amputation of the affected limb or more seriously death of the patient, mainly due to delayed detection and primitive treatment. With advances in the detection systems and imaging, bone tumours are detected in patients at much earlier stages of development. Treatments such as chemo and radiotherapy are able to reduce the size and spread of the tumour before surgical intervention. In some cases complete elimination of the disease is achieved by this treatment. Patients undergoing chemo or radiotherapy have a small window in their treatment regime when the disease stops responding to the treatment. It is at this time when the affected bone is surgically removed and a replacement section is inserted. So, what are the options for replacing the discarded diseased bone? A review of current practice is described in the following sections.

1.2 Clinical review of current devices

There are a number of solutions to bridge the gap left by the removal of the affected bone. All of these solutions have varying degrees of effectiveness and durability. Some of the main bone replacement procedures and critical factors associated with their effectiveness are explained below.

1.2.1 Biological substitutes

The most natural solution is to utilise biological material either harvested from the host (autograft) or harvested from a donor (allograft). Vascular autografts are the best substitutes since there are no rejection complications and the blood supply is easily regenerated, either by post-implantation vascular growth or by reattaching blood vessels during the implantation procedure. Autograft bone is ideal because it contains all the characteristics necessary for new bone growth, namely osteoconductivity, osteogenicity, and osteoinductivity. For small sectional defects, autograft is usually harvested from the iliac crest, fibula or possibly from the femoral or the tibial cavity. However, these donor sites limit the amount of bone that can be harvested and therefore homologous autografts involving joints are not possible since there are no spare limbs in the human body. Instead, allografts taken from donors or cadavers are used to provide anatomical segments. Anatomical allograft has the advantage of having specific sites for ligament and tendon reattachment, allowing better post operative limb function when compared with endoprosthetic replacement. However, allografts pose additional risks in terms of transmission of disease and infection, even though the bones are sterilised prior to implantation. Large scale use of allografts was reported by Donati *et al.* (2002) on 27 patients with proximal femoral allograft composites and later in 2003 on 588 patients for a variety of conditions. In this study, they claim to have a very successful outcome, but they also report that by three years post surgery there was 18% failure due to infection, resorption, delay in consolidation and fracture.

Although a biological solution is the best, a harvested bone fragment requires fixing on to the host bone to act in unison. Plates and screws are used to fix the bones whilst staples or sutures are used to fix soft tissues to the new bone. Fixation failures are often encountered with this type of procedure where plates and screws are insufficient to provide a stable structural strength over long periods, mainly undermined by the regenerative response induced by the altered osteogenic strains. To overcome the fixation problems, composite structures are created by employing prosthetic devices

in combination with allografts. Currently, this appears to be the accepted practice because it provides the benefits of a biological replacement and at the same time allows immediate load bearing post operatively, leading to a quicker recovery.

Although as indicated above, homologous autografts involving joints are not possible, recently it has been demonstrated that the diseased bone removed from a patient can be sterilised to destroy the disease and then re-implanted back into the patient. There is, however, a small risk of recurrence using this method. This technique has been successfully proven to be a good alternative for cranium tumour cases (Vanaclocha *et al.*, 1997; Manning *et al.,* 2000) but as yet use of this technique in long bones has not been proved in journals. This technique is well suited for cases where the bone stock is good and capable of carrying normal load during the postoperative months, before the sterilised bone regenerates and becomes live again.

Fixation is often compromised if the replacement allograft fails to re-vascularise, leaving the interface un-united. This complication is exasperated if there is excessive motion at the interface, which then hinders new bone formation leading to a mal-union. For the joint to unite properly, micro-motion at the interface should be in the range of a few microns and the joint should allow transfer of compressive load across the interface. One further complication associated with the allograft and autograft is bone resorption, which usually leads to narrowing of the bone stock or reduction in density (osteopenia). This is usually caused by stress shielding induced by the fixation hardware and/or composite implant or by lack of cyclic loading depriving the bone of osteogenic strains. Often the combinations of all or some of these factors are linked, resulting in a complex failure condition.

1.2.2 Orthopaedic implants in general

Orthopaedic implants are currently universally accepted as the most common form of bone replacement solution. These artificial bone and joint replacement devices are usually made from metallic and/or polymeric materials. With modern advancements in orthopaedics, people with bone tumours are successfully treated using these implants. This can be a simple surgical procedure from which the patient recovers quickly and in most cases has long-term success. For most patients these implants act as spacers, often with integral artificial joints to maintain limb function as normal as possible. In contrast to biological solutions fixation of these implants is usually performed by using either bone cement or press-fitting without cement. This allows the patient to weight bear within days post operatively, aiding a quick recovery from the traumatic surgery. This is a very important consideration for the treatment of tumour patients, who often have a poor prognosis and hence the ability to get on with their remaining short lives as quickly as possible is crucial.

Although a simple and effective procedure, there are a number of associated problems. Lee *et al.* (2002) has recently reported a retrospective follow-up study of 145 patients that underwent prosthetic reconstruction between 1985 and 1998 with 18 cases developing infection. He also reported that infection after prosthetic reconstruction is not only difficult to treat but also influences the prognosis. Grimer *et al.* (2002) has also reported a two-stage revision to eradicate infection in 24 patients with 91% success rate at 1 year and 74% at 5 years. However, 6 patients required amputation due to unsuccessful treatment. Renard *et al.* (2000) has a similar opinion that complications are more common after limb-saving therapy than with standard joint replacements. On the other hand, with the use of antibiotic prophylaxis, infection can be controlled for patients with endoprosthetic replacement even when the immune system is suppressed during chemotherapy, as reported by Ward *et al.* (1997). Nevertheless, infection is a major issue in proportion to the number of cases treated and it should not be ignored. The fact that infection forms and is associated with the implant site is an important factor

(Krepler *et al.,* 2003) and a number of researchers have reported investigations using antibacterial substances such as silver coatings (Colmano *et al.,* 1980; Gosheger *et al.,* 2004). F Zhang and his colleagues in Heidelberg, Germany have developed (not yet published) a technique to dope titanium oxide film with silver to provide a long-term protection, but the effectiveness of the application is not yet known. Gentamicin, which is an antibiotic, is also used as a coating to reduce implant-related osteomyelitis in rats, bringing the technique a stage closer to applying to humans (Lucke *et al.,* 2003). It is also reported that bacterial adherence is dramatically reduced, preventing bacterial colonisation on titanium surfaces coated with human serum albumin (Kinnari *et al.,* 2005); an important factor in preventing infection. Although it appears that modification to the implant surface is the way forward to achieve better material compatibility and improved infection controls, the question remains what happens when the surfaces are modified in the body by wear and/or aging?

Implant fractures and related complications are very few, but from time to time they do occur. As a result of the low numbers, the majority of these cases go unreported and there is little published in the journals. However, Gitelis *et al.* (2003) reported fractured implants in 5 patients. The presumption is that the main shaft of an implant is often designed with higher strength than required to support daily loads, but the fixation and to a lesser degree the associated joints are the weakest links in the system where fractures occur through fatigue. Wear of the joint is also a factor, which limits the life of the device. Although wear is not often considered a mechanical failure, it has a detrimental effect on the body leading to failure at the bone/implant interface. There are two types of wear particles. Metal particles are small and numerous and can migrate with blood flow over long distances, whilst plastic particles are relatively large and are localised around the implant site. Bone lysis forms as a result of a failure mechanism of implant fixation with the formation of a soft tissue layer between the bone and the implant (al Saffar *et al.*, 1994). Plastic/metal particles are usually found within this layer and therefore the formation of bone lysis is now considered by most people to be the result of reaction to these particles.

Aseptic loosening seems to be the other major problem in the survivorship of endoprosthetic replacements. More importantly this problem is more acute in juveniles who really need something long lasting. Kawai *et al.* (1998) reported that aseptic loosening of distal femoral replacement, which necessitated a revision in 11 patients at an average of 51 months, was the most frequent mode of failure. Grimer *et al.* (2000) found aseptic loosening inevitable in younger children and almost unavoidable. The largest study ever reported was by Unwin *et al.* (1996) with 168 cases of extendible prosthesis where predominant failure was due to aseptic loosening. In the growing bone structure, implant fixation is gradually compromised by the bone expansion. This was clearly demonstrated by Blunn *et al.* (1991) where trabeculae bone remodelling around a cemented intramedullary stem gradually created cavities and hence it is not surprising that juvenile patients suffer the most with aseptic loosening. This article describes bone expansion after 10 years around a cemented stem where the cement mantle surrounding the stem was clearly separated from the cortical bone and the cement mantle was supported entirely by trabeculae bone. To prolong the life of the fixation, a stippled collar on the shaft of the prosthesis with hydroxyapatite coating was used to provide cortical bridging formed by pedicle growth across the plateau. A typical distal femoral replacement treated at the Institute of Orthopaedics & Musculo-Skeletal Science is shown in Figure 1.1. It is clear that without the collar this stem fixation would have failed a long time ago.

Replacement of a mid section of a long bone is the simplest to treat using a diaphysial implant. With this type of replacement patient recovery is much faster and the functional result is as good as natural bone. This is because very little muscle attachment from the bone is lost and the natural joints at both ends continue to function normally. When the tumour is closer to a joint, in order to provide adequate fixation, the joint is sacrificed to gain a stable fixation on to the adjacent bone. This type of implant usually contains an artificial joint that is not always as good as the natural joint and therefore limb function is significantly compromised. This is a normal approach routinely

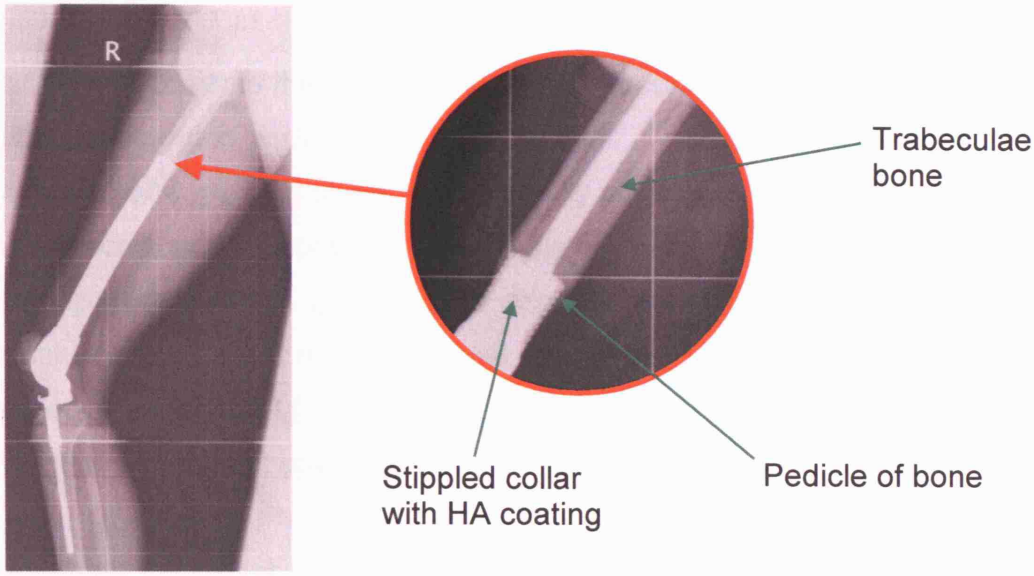


Figure 1.1 A distal femoral replacement with HA collar integrated with the adjoining bone and cement mantle supported entirely by trabeculae bone (Picture supplied by the Department of Biomedical Engineering, Institute of Orthopaedics, Stanmore)

taken by most clinicians. However, because the diaphysial implants have worked so well, modern thinking by some clinicians is to preserve the joint and in doing so maintain joint function as normal as possible. This technique prevents invasion into the adjoining bone, keeps the joint capsule containing meniscus and underlying cortical bone intact, retains joint ligaments/tendon attachments and eliminates detrimental effects of an artificial joint such as wear, fatigue and a compromised joint motion. These are the new generation of joint sparing diaphysial replacements.

Not all the materials are readily accepted by the body's immune system and some materials are susceptible to corrosion, wear and fatigue and therefore material selection for implants must be done carefully. The British Standard, BS EN 12010, provides a listing of commonly accepted materials and their combinations suitable for various applications in the body. This, together with a good design is usually adequate to provide an effective solution for tumour cases.

1.2.3 Treatment for immature patients

For mature patients these implants act as spacers often with integral artificial joints to maintain a degree of limb function. However, children with their immature and growing skeleton, especially where an epiphysial growth plate is sacrificed, need a special kind of implant that can be extended periodically to keep pace with the growth in the opposite limb. Apart from an extending capability, the device must be robust enough to last until adulthood. This is particularly important for very young patients (infants) who have a very small skeleton with limited space for an implant.

Extending prostheses with surgically invasive extending procedures have been used for the past thirty years, (Unwin *et al.,* 1996; Schindler *et al.,* 1998) with intrinsic problems of infection and long-term recurrent trauma to the patient. The first ever extendible massive endo-prosthetic replacement in the UK was produced at the Institute of Orthopaedics, Stanmore in 1976, as reported by Scales *et al.* (1987).

Figure 1.2 shows the schematics of this Mk1 device (Scales *et al.,* 1987) where a telescoping shaft is separated by a screw pushed outwards by a nut integral with a gearwheel driven by a cross-acting worm. One end of the shaft was designed to mimic femoral condyles to articulate with the tibia and the other end carried a stem for cementing into the remaining upper part of the femur. Once implanted the prosthesis was extended by inserting and turning a key through a small incision. This took place in the operating theatre with the patient under general anaesthesia. By 1982, four devices

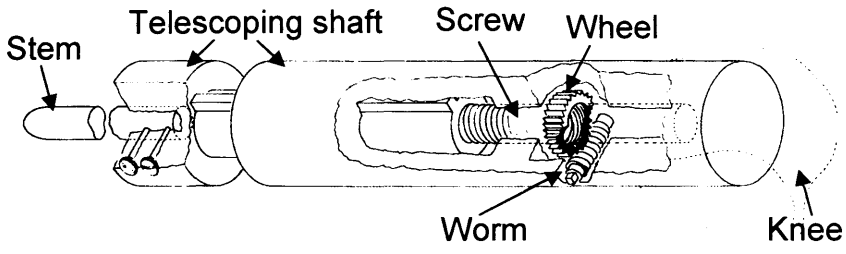


Figure 1.2 Mk1 extending prosthesis introduced in 1976 (Artwork produced by Mr Joe Greenough, Department of Biomedical Engineering, Institute of Orthopaedics, Stanmore)

had been inserted: two were difficult to extend; one was extended; no further information could be found for the fourth implant. The device had a number of design faults:

- It was too complicated to construct.
- The bearing surfaces between rotary parts were too big requiring relatively large torques to overcome frictional losses.
- The material combination used for the internal bearing surfaces were inappropriate for the application. Titanium was used for the whole implant causing it to wear rapidly and cold weld under large concentrated loads, i.e. between the screw and the nut and between the nut and the thrust face.
- The load produced by daily activity was carried by the screw threads inside a short nut leading to rapid wear and fretting of threads in this region.

As a result of these problems, a Mk2 device (Scales *et al.*, 1987) was constructed where the telescope section was expanded by insertion of quarter inch diameter tungsten carbide ball bearings. Again a small incision was required to carry out this procedure. The original device had an entry port normal to the long axis of the prosthesis, which necessitated extreme force to insert a ball bearing into the implant. This large insertion force often fractured the ball bearing during surgery, rendering the extending mechanism inoperable at times. Consequently, a Mk3 device with an inclined port to reduce the insertion force was introduced as shown in Figure 1.3. By 1988, 59 patients were treated with similar devices. At this stage it was clear that this device had problems not just during the extending procedure but also during normal use where point contact between adjacent ball bearings caused stress concentration resulting in ball fractures in daily life.

Once again, as a result of ball bearing fractures, the design was reviewed and a Mk4 device (Figure 1.4) was introduced where 'C' shaped collars of increasing lengths in multiples of 6mm were supplied for each patient. Once

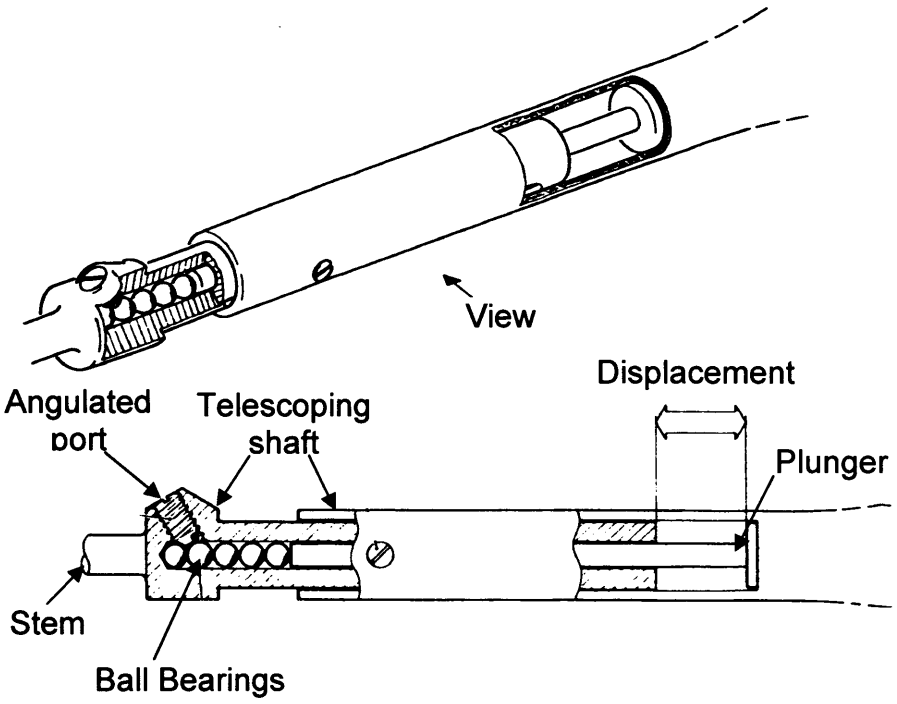


Figure 1.3 Mk3 extending prosthesis with ball bearings introduced in 1982. (Artwork produced by Mr Joe Greenough, Department of Biomedical Engineering, Institute of Orthopaedics, Stanmore)

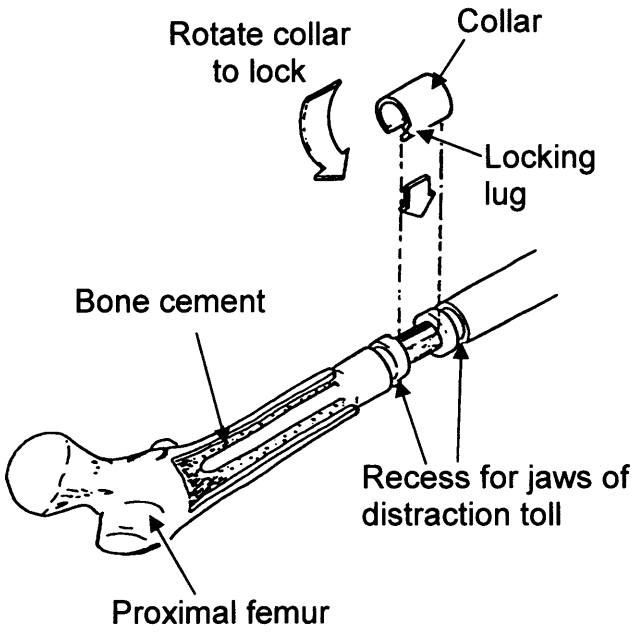


Figure 1.4 Mk4 extending prosthesis with collars introduced in 1988. (Artwork produced by Mr Joe Greenough, Department of Biomedical Engineering, Institute of Orthopaedics, Stanmore)

implanted the prosthesis was surgically lengthened by replacing the collar with a longer collar. The biggest drawback with this system was that a large incision was required to replace the collar. Therefore, the patient went through a major operative procedure every time the prosthesis required lengthening. Over extension was advocated to reduce the number of operations, which often resulted in excessive stiffening of the adjacent joints and formation of large volumes of scar tissues associated with the invasive surgery, leaving the patient with marked deterioration in range of motion. By 1992 this mechanism was used in over 100 patients. Mechanically, this device functioned extremely well.

As a result of the reduction in range of motion and also the large-scale surgery associated with the collar type device, a simplified version of the Mk1 design (Mk5) was redesigned and introduced by me in 1991. In the Mk5 design telescoping parts were made from titanium whilst the screw and the worm were made from cobalt chromium alloy, eliminating cold-welding of screw and associated parts and at the same time improving the bearing surfaces. The torque required to drive the worm was also minimised by reducing frictional torque acting on the bearing surfaces. The design also provided separation of the telescoping section, allowing partial revision of the implant where required. Screw thread contact within the telescoping section was increased to minimise the wear and fretting and the daily activity loads were directed through the screw onto the opposing part of the prosthesis, thus bypassing the worm and avoiding unnecessary damage to the gear mechanism. Since its introduction, over 400 such implants were made and the design is still in use today. Although, the lengthening procedure is done through a small incision, patients are exposed to a degree of risk of infection and also the trauma of attending surgery every time it requires lengthening. For this reason, these implants are over lengthened to reduce hospital attendance, and complications associated with over lengthening remain. There have been a number of cases where this device has collapsed and in two cases it has extended without external intervention, the reason for this is unknown. One telescoping section has fractured through fatigue. These devices are extended when there is a shortening of the limb by about 5 to

10mm. Smaller extensions are performed for patients with a good recovery history, whilst for patients with slower recovery and those who have found the experience of having a tumour and what is to follow difficult to come to terms with, larger extensions are performed to alleviate the traumatic situation. The frequency of extension is usually governed by growth rate and the clinical and mental status of the patient, which can vary between 2 and 12 months.

An implant involving an adjacent joint and where the implant fixation is gained on the opposite side of the joint onto the adjoining bone, a technique called "Passive Implant Growth" (Inglis *et al.*, 1992) is used to maintain the growth in the adjoining bone by natural processes. In this case the implant is seated between the joint and the epiphysial growth plate such that the growth plate is minimally disturbed, allowing it to continue to grow naturally. To gain implant stability, a small hole is perforated through the centre of the growth plate to allow the stem, usually made to fill the intramedullary cavity, to pass in the canal. As the bone grows the implant is lifted with it.

Lewis *et al.* (1987) developed a minimally invasive device manufactured by Dow Corning Wright of Arlington, Tennessee, USA where the prosthesis had an internal sleeve which could be extended to a maximum length of 150mm with a small key similar to that used in Jacob's chuck. The lengthening was typically 15 to 20mm per operation, which was performed at approximately 6-9 month intervals. He also reported that there was no point having a complex device of this nature if the expected growth was less than 2 cm, which can quite easily be compensated for by raising the heel. Obviously this fact is widely accepted even now.

Unfortunately, the infection rate for even a minimally invasive device is reported to be around 16%, which in most cases can only be treated by explanting the device and replacing it with another similar device. Infection also produces undesirable tissue reaction leading to bone sepsis, often ending in loosening of the implant and thinning of the surrounding bone. The explanting process can further damage the surrounding bone. Therefore the replacement device is usually a little longer than the explanted device to

provide adequate fixation onto the new bone. As a result of the unsettled and destructive experience, the body reaction to a revision implant is not always the same as to the primary implant. It is reported by Unwin *et al.* (1996) that the survivorship of a revision implant is significantly reduced compared with a primary implant.

Prosthetic replacements in younger patients are usually associated with bone tumours and not surprisingly these implants require mechanical lengthening to keep pace with natural growth. Bone lengthening is, of course not limited to just children. In adults it can be used either for cosmetic reasons or for treating a deformity where the bone requires lengthening or straightening over a relatively short period, without using an implant. A technique called distraction osteogenesis, originally introduced by Ilizarov, is used where following a partial osteotomy of the bone the two halves are held together with an external mechanical frame, often referred to as a Ilizarov frame, with pins inserted into the bone as struts (Ilizarov, 1989). The frame is rigid enough to hold the bone steady even when loaded. With this device, both fragments of the bone are deliberately kept apart by a fraction of a millimetre for bone ossifications to occur within the gap through the natural healing process. Mineralization of the bone inside the gap occurs at the natural healing rate and to maintain the gap, the frame is extended by mechanical means approximately 0.8mm per day (Tsuchiya *et al.*, 1997). This slow expansion of the frame gives the impression that the bone is being stretched. At the end of the distraction cycle, the bone is allowed to unite and the frame is removed. This technique allows the formation of new bone over relatively long lengths in just a few months (Maffulli *et al.*, 1999), but the method has inherent complications as reported by Ozaki *et al.* (1998). Since the introduction of a circular external fixator in the early 1980's, this technique has allowed rapid advances in limb lengthening, deformity correction, and segmental long-bone defect reconstruction. There is, however, a degree of discipline required by the surgeon and the patient for alignment and the loading cycle to achieve uniform bone extrusion. The nature of the device is such that it also imposes complications to the patient's mobility and aesthetics, with added risk of infection. Although this technique appears to

be widely used, it is still in its infancy and we have a great deal to learn, particularly regarding the longevity of the treatment.

There are approximately 50 cases of child sarcoma requiring limb salvage per year in the UK and there are many more around the world. Infection and repeated trauma to the patient are the main driving forces to devise a better implant that can be remotely extended, is affordable and can be used routinely.

1.3 Development of non-invasive concept – technological review

In the late 1980's researchers began to contemplate development of a non-invasive lengthening device to:

- Reduce trauma and pain to patients caused by repeated surgery.
- Reduce long hospital stays.
- Reduce treatment costs.
- Reduce post treatment complications such as infection, lack of tissue healing and marked reduction in the range of motion caused by over lengthening in the invasive devices.
- Generally give better life to patients at the time when they are in their infancy and in some cases have a poor prognosis.

Over the past twenty years, attempts have been made to develop a truly non-invasive extending implant for immature patients. There are a number of design concepts that have been investigated amongst which, the most obvious is the mechanical (clockwork) device developed by Kotz *et al.* (2000). This is a complex system of gears and levers with an activation lever with a ratchet operated by flexing the knee, the displacement of which causes the gears to inch forward by a fraction of a turn. The first generation device contained 29 moving parts, whilst in the latest device there are 49 moving parts. The main drawback of this device is that it only works with a distal femoral replacement as shown in Figure 1.5 and it may be made to work in a proximal tibial replacement. However, this device clearly has a single point of application that is around the knee region and it is not suitable for other sites in the body.

Another ingenious device is produced by Phenix Medical in France (the same concept is used by Wright Medical) in which the telescoping parts are expanded by gradually releasing a compressed spring mounted in a resin block. As the resin is heated through an attached small antenna using microwaves, the heat generated softens the resin and allows the spring to

expand (Figure 1.6). With the implant under a live radiological imaging system, a few second microwave pulse is applied to the implant antenna to expand the prosthesis by a small amount. This is repeated if more extension is required. A concern here is that if the vast amount of energy stored in the spring is

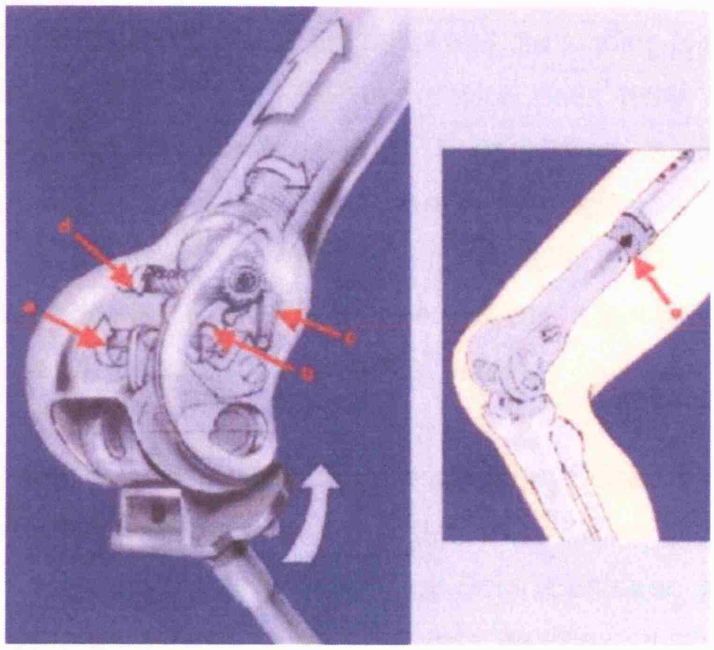


Figure 1.5 Kotz self-activating growing prosthesis. (Image from Kotz *et al.*, 2000)

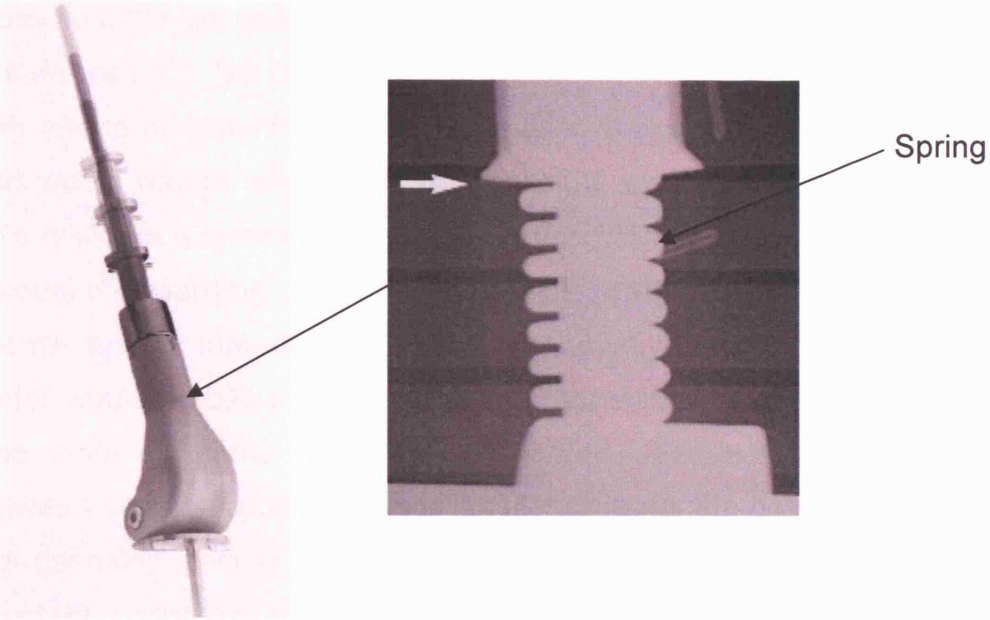


Figure 1.6 Phenix growing prosthesis. (Images from brochure from Wright Medical Technology Inc., Arlington, TN. for Repiphysis™, Limb Salvage System for the Skeletally Immature)

accidentally released it can have a traumatic effect on the patient. Also, daily load is directly carried by the spring and as one would imagine, the telescoping section is likely to piston in and out as the patient walks, which may be noticeable during a heavy load cycle, i.e. when running. However, the device is ideal for very young infants where tiny implants are required and in the upper limb where the compressive forces are small and the loading is relatively small compared with the lower limb. So, this device does have a much wider application than the clockwork device. Nevertheless, a risk of sudden expansion and wear of the device, due to the pumping effect in the telescoping section, remains a concern. Despite all this, Gitelis *et al.* (2003) reported implanting this device in 18 patients with good result, although they claim that complications should be expected and in their experience are salvageable.

Over the past twenty years at least two groups in the world have attempted to develop a non-invasive growing prosthesis for children using motorised coupling. A variant of this as proposed by Betz (European patent number EP0959793) uses an electric motor to drive a gearbox as shown in Figure 1.7. Here the motor is powered by an induction coupling between an implant coil and an external coil. It is not clear if the invention uses a DC or an AC motor to drive the gearbox. We see that there are two major problems with this device. If a DC motor is used then the motor speed is likely to change with torque and therefore it would be difficult to maintain a constant speed and would require some kind of monitoring system to control the growth. This could be a feedback system using telemetry or x-ray imaging to see the amount of expansion. Direct monitoring using telemetry would be preferable, but the system may become very complicated. On the other hand, an AC motor would probably be too large and, depending on the type used, could also suffer the same fate as the DC motor. Also in this design, the load between the telescoping sections is taken through the gear mechanism onto the opposing section. This would place the drive mechanism under a constant unnecessary load cycle through daily activities of the patient, causing it to wear and possibly lead to destruction by excessive accidental loads. Verkerke *et al.* (1994) reported that this device was tested *in vitro* and that six animal trials were successful. Verkerke *et al.* (1997) later reported

that the patient who had the device was only extended by 19.5mm before the patient died from other causes. There are no further reports of this device being implanted into patients.

The second group to use the magnetic coupling to drive a gear mechanism is our Institution here at Stanmore UK and this work is being presented in this thesis as described in section 1.5 below.

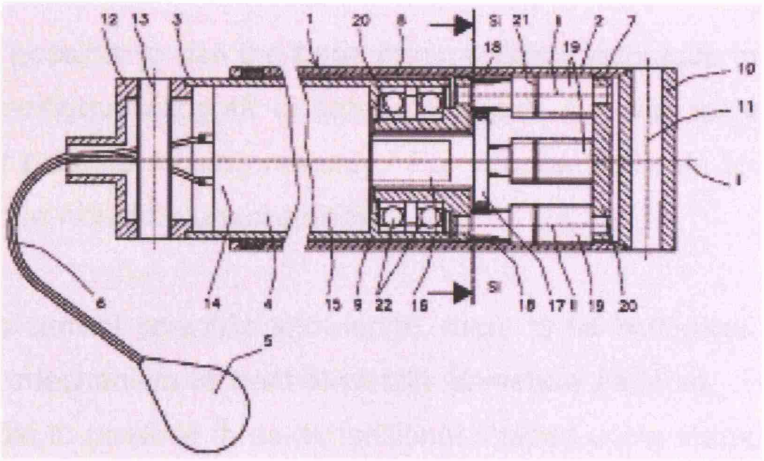


Figure 1.7 Motor driven extending prosthesis from BETZ (Image from European Patent Number EP0959793)

1.4 Lessons learnt

Growing or extending prostheses have been in existence since the early 1970's and a number of people around the world have attempted to devise an effective solution for treating juvenile patients. Experience shows that there are certain aspects of the requirements that can be met, whilst others cannot. So what are these?

(a) It is clear that allografts and autografts are not suitable for immature patients since growth in the implanted bone cannot be achieved. Only if the expected growth is less than 2cm can homologous allografts with reconnected soft tissues be used. This technique is carried out in the upper limb with a good success rate in children as reported by Shih *et al.* (2002).

(b) It is possible to use the bone transportation technique in combination with a homologous allograft to extend the limb, but this technique is only suitable for patients nearing maturity. For younger patients frequent use of this technique would be unacceptable.

(c) With current scientific knowledge, there is no biological solution with the growth mechanism to treat skeletally immature patients. However, it is now possible to produce three-dimensional shapes using stereo lithography. Also, using scaffolding, body parts are produced in laboratories for soft tissue homogenous transplants. By scanning the opposite side or by taking the average anatomical shape, it may be possible to combine these two techniques to produce biological bone substitutes. Nevertheless, it will be some time before a complex epiphysial structure can be produced in this way which is capable of regenerating and maintaining growth in synchronisation with the patient's growth.

(d) Improved fixation of the implant has already been achieved by using an uncemented stem or plated fixation in combination with a textured bone implant interface, such as a collar with hydroxyapatite coating which encourages new bone formation at the interface. The next stage is to bond

the plateau of the prosthesis onto the bone without causing stress shielding, but this has not yet been achieved.

(e) Implant complications are related to the design and therefore these must be minimised at the onset of the introduction of a new design. However, the materials used are inanimate and are sensitive to fatigue, corrosion, damage and wear and tear through daily usage and therefore are likely to fail. In juveniles, it is clear that implant strength designed for an infant will not be suitable for a teenager or adult and therefore a juvenile patient will quickly outgrow the implant, effectively making it weaker with time. An implant that is super-strong which has enough sectional strength to last till adulthood is required to overcome this inherent weakness with aging. This, however, does not address the requirement of the artificial joint to grow in size as the patient grows. Super-strong material may be possible but a growing artificial joint is not. One further possibility is to make the metal part grow using nanotechnology, but this is futuristic.

(f) For juvenile patients, a solution to date is to use orthopaedic implants which have been designed with telescoping segments that have scope for expansion and when fully expanded have adequate stability between the sliding parts to withstand daily load cycles. Perhaps this is a limiting factor, but could something else be done? A bone transportation concept where bone is lengthened by osteotomy, followed by gradual and controlled separation of the two fragments allowing new bone formation at the interface, is already in use. Could it be possible to combine an orthopaedic implant with the bone transportation technique for juvenile patients? An application for this would be in infants, where the available space is always limited and a telescoping section may not be possible. It is not within the scope of this project, but it would be a good concept for evaluation in the future.

(g) A non-invasive mechanical clockwork extending mechanism used by the previous invention is fine, but has a limited application. There does not appear to be any possibility of adapting this device for other sites as the power and action provided by the knee joint does not exist elsewhere. A

linear electromagnetic actuator could be used in combination with a gearbox to amplify the power, but it may not be strong enough to overcome large distraction forces. The Phenix implant with a spring has obvious drawbacks but as explained before, may provide a solution for infants and upper limbs and its capability must not be under estimated. The motorised device is a good concept but suffers from design faults. However, if made to work effectively, this is the only device that can be used anywhere in the body and if the size is minimised, it may even be suitable for infants.

1.5 Stanmore non-invasive concept and design goals

It is quite clear from this review of existing devices and the technology before us that a telescoping section driven by a gearbox and a motor is the most feasible proposition. The main advantage of this device is that it can be used anywhere in the body. However, the size and the design concept are the main issues. In order to reduce the diameter of the prosthesis, the telescoping section needs to be remote from the drive mechanism allowing it to be reduced in diameter to match the patient's bone. Therefore the drive mechanism can only be placed in series with the telescoping section, limiting the potential growth that can be built into the prosthesis. However, if the motor is broken down into two distinct parts, a rotor and a stator where the rotor is minimised in size and is attached to the gearbox inside the prosthesis and the bulky stator is placed outside the patient, then the overall length of the drive mechanism inside the patient can be minimised. The concept of a slender magnetic disk requiring only a small space, which can be magnetically coupled and driven by a large electrical coil, was born. Here the external coil can be as big as required since there is no restriction of space. The concept is simple where the magnet acts as a rotor and the coil acts as a stator of an electric motor. The only difference here is the large air gap between the stator and rotor, which is extremely unconventional. However, the advantages are quite obvious as far as the space inside the prosthesis is concerned.

The important aspects of this design in comparison with the invasive device currently used at this Institution are:

(a) It will reduce the risk of infection which currently is very high compared with standard joint replacement prostheses.

(b) The patient will not require an operation to extend the implant.

(c) This technique should inconvenience the patients less as they will not require a hospital in-stay.

(d) Although the cost of the prosthesis will exceed that of a contemporary design, the overall cost for patient treatment would be reduced as multiple operations are not required to extend the prosthesis.

Scoliosis is another area where the extending mechanism is used to treat juvenile deformity. It is said that if a corrective treatment is applied at a young age, when the body is going through a natural growth, the correction can be lifelong. Adjustable rods are used to treat these patients invasively and therefore a non-invasive device would also provide benefits similar to those already discussed. Typical Harrington distraction and compression rods are shown in Figure 1.8. There are number of different versions currently on the market, none with a non-invasive mechanism and therefore this is another area where this new technology could be applied.

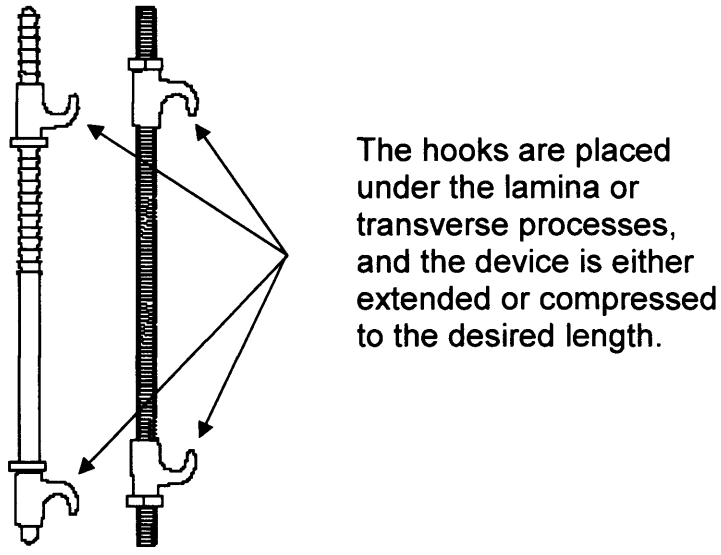


Figure 1.8 Harrington distraction and compression rods.

1.6 The project aim

The aim of this project is to:

(A) Carry out a limited clinical trial of a non-invasive growing prosthesis in the lower limb by following these stages.

(a) Ascertain the clinical requirements of a mechanical design for the treatment of juvenile bone tumour patients.

(b) Establish a working non-invasive extending device for bone tumour patients using electromagnetic coupling by:

- Evaluating the performance of the design in terms of the clinical requirements.
- Re-evaluating the original design for miniaturisation.
- Re-designing the mechanical mechanisms based on the performance obtained.
- Testing the final design.

(c) Conduct a clinical trial using a non-invasive extending device to prove the viability of this device in bone tumour patients and report on the use. This study will be carried out in the RNOHT on up to 6 young patients who have bone cancer in either their femur or tibia. These patients normally would have used a minimally invasive extendible growing prosthesis. The goal is to prove the efficiency of a non-invasive device and ultimately in the future to use these devices in place of minimally invasive growing prostheses for these young patients. This would have obvious benefits as the patient would no longer require an operation or a stay in hospital and the risk of infection of these implants would be reduced.

The clinical trial is the culmination of a project which has taken around 5 years to date. This project has involved:

- The measurement of the forces needed to distract a non-invasive device, which can be up to 1,000 Newtons.
- The design of a prosthesis, which is able to extended non-invasively.
- The effect of a cyclic load on sealing the cavity with the magnet and the gearbox for a successful functional operation.
- Testing that the forces generated using this device are able to achieve expansion under the conditions of soft tissue tension that we have previously measured when extending invasive devices.
- The mechanical testing under cyclic load of the device in the laboratory.

(B) Develop a similar system for juvenile scoliosis patients for the treatment of spinal deformity by following these stages.

(a) Ascertain the clinical requirements of a mechanical design for the treatment of juvenile scoliosis.

(b) Expand the electromechanical concept developed for bone tumour patients specifically for the treatment of scoliosis.

1.7 Hypotheses

a) **A non-invasive magnetically coupled extendible endo-prosthesis designed for children with malignant bone tumour can provide optimised growth potential in a manner that is simple, pain free and easy to use and provides consistent and repeatable growth.**

b) **A similar prosthetic system can provide the same outcome for juvenile scoliosis patients.**

1.8 Other related applications of the new technology

Limb lengthening is one application of this new technology that at this stage is assumed to be capable of providing a vastly improved life for cancer patients who, in the majority of cases, do not have a good prognosis. Equally, other patients who have no life threatening disease but have to go through similar repeated surgery or carry a device that is too uncomfortable for long periods, would benefit from a similar treatment. As described above, distraction osteogenesis is currently performed using an external fixator with several pins going through the skin, holding the bones steady in relation to each other. This device is uncomfortable, painful and is prone to infection around the skin. A non-invasive device would provide a vast improvement in treatment for these patients.

CHAPTER 2

IN VIVO FORCE MEASUREMENT

2.1 Introduction

Although there are a number of different techniques available for limb salvage surgery, prosthetic reconstruction remains the most accepted means of treatment. Advantages with a prosthetic replacement are that it provides a simple and quick solution to bridge the gap created by the removal of the diseased bone and because of a positive fixation achieved at the time of surgery, post-operation recovery is relatively quick. This is particularly important with bone cancers where there is high mortality and a solution which allows terminal patients to quickly use their salvaged limb, is an essential requirement. This is also important for those patients who have suffered physically and mentally from the disease and from subsequent treatment. In adults, insertion of prostheses is generally sufficient and further surgical intervention is usually not required for many years. However, in children where the skeleton is still growing, these fixed length endo-prosthetic replacements are not adequate because their use would result in limb length discrepancy as the patient grows. Children require a prosthesis that takes account of the growth that would have occurred in the section of bone that is removed. Expandable prostheses that are able to lengthen periodically are therefore used for juvenile patients.

There are a number of extendible prostheses currently used and the majority require surgical intervention to lengthen them. There are, however, a few new designs that are non-invasive but these lack integrity and/or strength, as explained in the first chapter. To design a new generation of implants incorporating modern technology and materials for optimum performance and treatment, the load carrying capacity required during an extending procedure needs to be measured. To understand the loading condition on a growing prosthesis, a trial was undertaken with patients that were receiving lengthening procedures using surgical intervention. At the time, the Stanmore Mk4 growing prosthesis shown in Figure 2.1 was in use at this Institution and at Royal Orthopaedic Hospital, Birmingham. This chapter describes implant design, patient selection, distraction procedure, data acquisition and the result of the study.

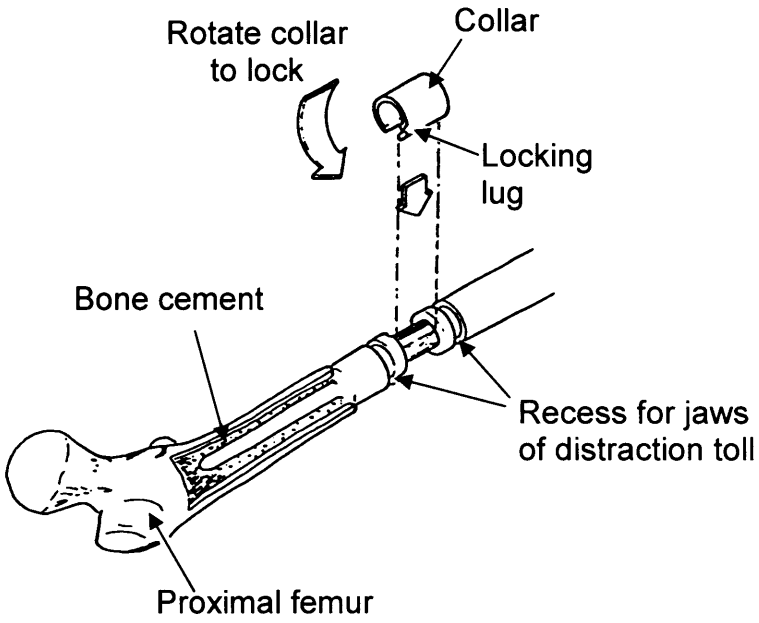


Figure 2.1 Mk4 extending prosthesis. (Artwork produced by Mr Joe Greenough, Department of Biomedical Engineering, Institute of Orthopaedics, Stanmore)

2.2 Method and materials

2.2.1 Implant design

The Mk4 extending prosthesis (Unwin *et al*, 1996) introduced in 1988 had a hollow shaft acting as a tube into which a reduced diameter spigot was fitted, allowing it to expand longitudinally like a telescope. An anti-rotation key inside the shaft and a corresponding longitudinal slot in the spigot prevented relative rotation between the shaft and the spigot. Outside the shaft there were two circular grooves, one on each part of the telescoping section, to locate an expanding tool to lengthen the prosthesis. One end of the telescoping shaft had a stem to fit the intramedullary cavity of the bone and this was usually cemented in place. For distal femoral or proximal tibial replacements, a total knee replacement was attached at the other end of the shaft, allowing fixation onto the adjacent bone. In the case of a proximal femoral replacement, a spherical head fitted over a trochanteric section was attached instead. These prostheses were supplied with a series of 'C' shaped collars in multiple lengths of 6mm to allow length adjustment as the patients grew. A typical distal femoral replacement is shown in Figure 2.2.

2.2.2 Patient selection

The primary criteria for patient selection was based on the patients who have had or were about to have a Stanmore Mk4 extending prosthesis and were receiving lengthening treatment at the Royal Orthopaedic Hospital, Birmingham. Apart from these basic requirements, there were no other specific criteria in patient selection.

At the initial surgery, the affected bone was removed from the patient and the prosthesis was inserted in the usual way with the telescoping section fully retracted. The collars were stowed away for future lengthening operations. Table 2.1 shows the patient listing in order of patient selection. At the start of the project, the majority of patients had already had several lengthening operations performed before I started taking the measurements. In contrast,

later in the project several new patients who were having their first lengthening operations were available.

In this study there were 34 patients: 12 female and 22 male. The primary diagnosis was 12 Ewing's sarcoma, 17 osteosarcoma and 5 revisions of previously implanted prostheses. There were 19 distal femoral, 2 proximal femoral, 1 total femoral, 8 proximal tibial, 2 proximal humeral, 1 distal humeral and 1 total humeral replacements. The sides were evenly divided with 17 lefts and 17 rights. The age of patients ranged from 2.8 to 16.3 with an average of 10.1 years at the time of insertion of the prostheses.

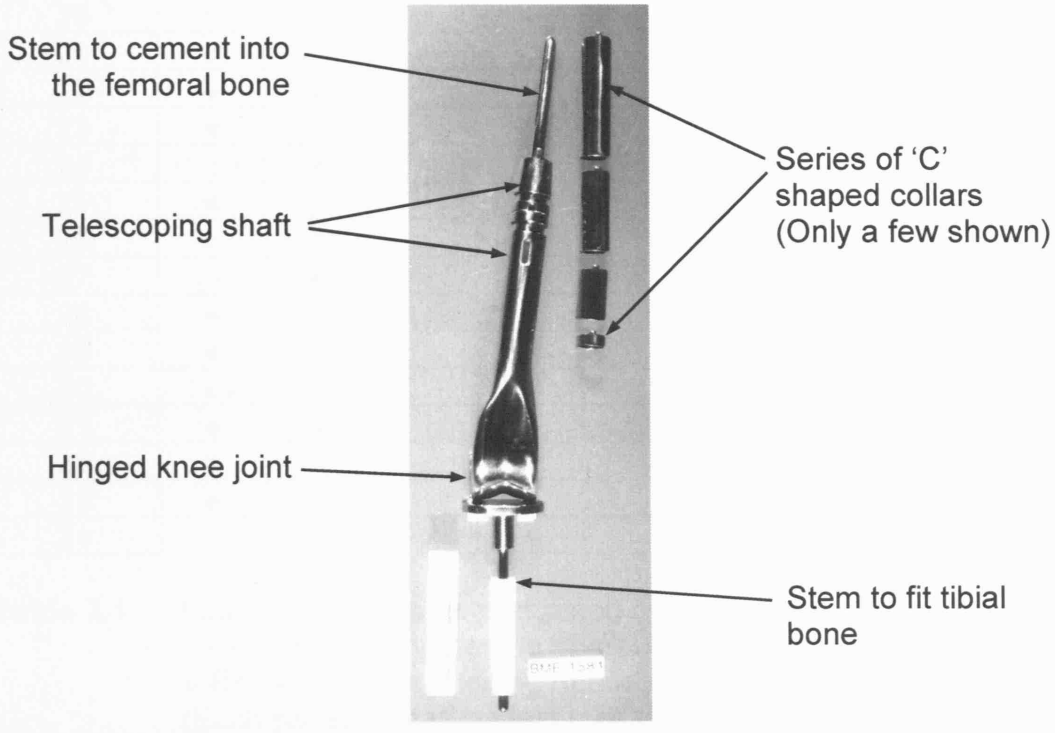


Figure 2.2 Extending prosthesis and its components. (Picture supplied by the Department of Biomedical Engineering, Institute of Orthopaedics, Stanmore)

Patient Number	N^{th} number of lengthening operation								
	1st	2nd	3rd	4th	5th	6th	7th	8th	9th
1	○	○	○	○	●	●			
2	○	○	○	●	●	●	○	●	
3	○	●	○	○	○	○	●	●	
4	○	○	○	○	○	○	○	●	●
5	○	●	●	○	○	○	●	●	
6	●								
7	○	○	○	○	●	●	●		
8	●	○	●	●	●	●			
9	○	○	○	○	○	○	○	○	●
10	○	○	○	○	●	○	●	●	
11	○	○	○	●	○	●	●		
12	○	●	●	○	●	●			
13	●								
14	●	●	○	●	●	●			
15	○	●	●	●	●	●	○	●	
16	○	○	○	○	●	○	●	●	●
17	○	○	●	●	●				
18	●	●	○	●					
19	●								
20	○	○	○	●	●				
21	○	○	●	●					
22	●	●							
23	●	●							
24	○	●							
25	●								
26	○	○	○	○	○	●			
27	○	●							
28	●								
29	●								
30	●								
31	●	●							
32	●								
33	●								
34	○	○	○	●					

Table 2.1 Load measurements performed on 34 patients.
○ Represents lengthening operation without load measurement.
● Represents lengthening operation with load measurement.
(Each patient, after the last measurement, may have had further lengthening operations that are not recorded here.)

2.2.3 Distraction procedure and data acquisition

Routinely, in order to insert a 'C' collar the patient requires surgery under general anaesthesia. The circular groves on the prosthesis shaft are exposed through small incision and the grooves are cleared from soft tissues and other large obstructions. An expanding tool is then attached by locating the jaws into the grooves and the shaft is expanded by about 9mm, which allows enough length to insert a 6mm collar. The collar is then twisted through 90 degrees and the anti-rotation lug on the collar is located into a corresponding recess in the shaft. The expanding tool is then allowed to reduce, trapping the collar and locking it in position. The wound is then closed and the patient is kept in hospital under observation for two to fourteen days before discharge. The same procedure is used for subsequent lengthening operations where the original collar is removed before inserting a 6mm longer collar. As one would expect, as the length of collar becomes longer with time so does the length of the incision, which in some cases is almost 150mm long.

For the clinical force measurement, a specially instrumented expanding tool was designed and manufactured to measure force on the prosthesis as it was extended. The expanding tool shown in Figure 2.3 consists of a fixed and a sliding arm linked together with a common shaft. Both arms have jaws extending into the wound of the patient, allowing easy location onto the implant whilst maintaining adequate accessibility around the prosthesis to insert and retract a collar. The jaws were made to swivel to compensate for any misalignment between the circular grooves of the shaft. The sliding arm of the expanding tool incorporates a load cell to measure the load applied at the jaw. By rotating the thumb wheel linked to the screw, the jaws were made to move in relation to each other, thus forcing the telescoping parts apart. The gap between the jaws was measured using a vernier calliper and the extension was stopped at 1mm increments to take a reading from the digital display. The first reading was taken at the instant when the gap between the sliding parts opened, thus representing the initial or residual

load on the implant. Subsequent readings were taken at 1mm intervals up to 9 mm.

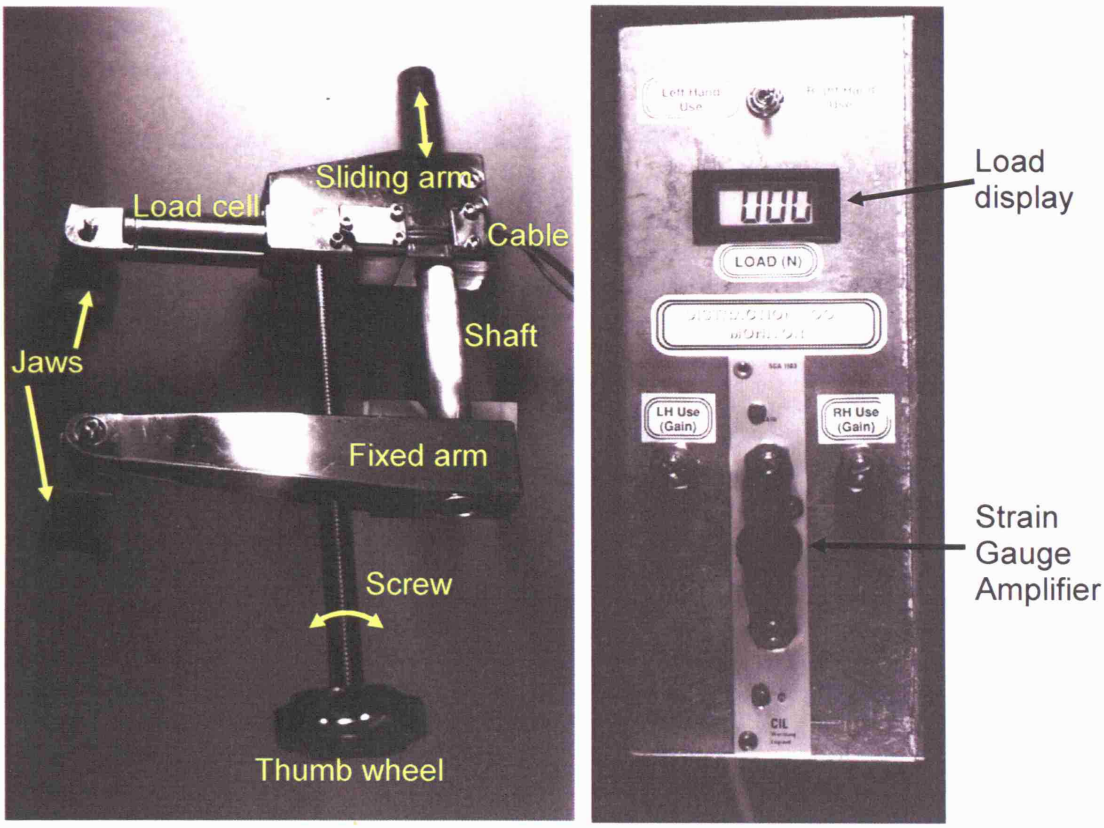


Figure 2.3 Expanding tool with digital load display.

The load cell in the sliding arm was constructed from a hollow tubular section into which two diametrically opposing 90 degree rosette strain gauges were mounted. To eliminate the torsional sensitivity of the loadcell, the gauges from each rosette were connected in series into two arms of a Wheatstone bridge, thus only measuring a unidirectional bending strain Mz shown in Figure 2.4.

To protect the gauges from autoclaving and during clinical use, the tube was hermetically sealed at both ends by welding. Wires from the gauges were taken out through three feedthroughs, to connect onto a high stability strain gauge amplifier with analogue to digital conversion at 3Hz to display the output digitally. The expanding tool was designed for repeated autoclave.

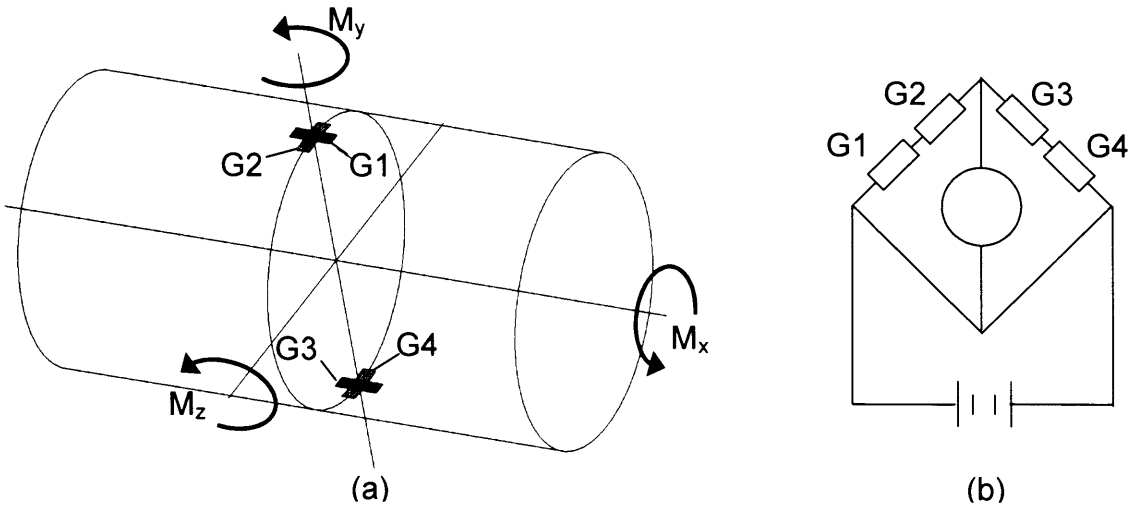


Figure 2.4 a) Strain gauge orientation and the applied moments,
b) Gauge sequence in the Wheatstone bridge to measure M_z moment.

The equipment was calibrated for both left and right-handed use with an incremental load to a maximum of 450N applied at the point of application. The accuracy of measurements was calculated as ±1.5% of the full-scale readings. Subsequently the instrument was autoclaved three times and calibration checked at ten different times to ensure stability with both heat cycles and duration. Although, we found no noticeable effect of the autoclaving procedure, the repeatability of the instrument over ten samples was calculated as ±3%, which is within 3 standard deviations representing over 99% probability of repeating the measurement as shown in Table 2.2. Calibration checks done after autoclave cycles are plotted in Figure 2.5, which shows a linear relationship between applied load and the output.

% Error with respect to applied load	
L H Use	R H Use
0.07	0.07
-0.37	-0.37
0.51	0.51
0.51	-0.37
-0.15	0.29
0.95	-0.15
0.07	0.51
-3.03	1.84
-0.37	1.40
-0.15	0.51
Statistics	
No of samples	20
Minimum	-3.03
Maximum	1.84
Average	0.11
% Confidence level for the average	95
+/- Confidence level for the average	0.42
Standard Deviation	0.95
+3 STD deviation	2.97
-3 STD deviation	-2.74

Table 2.2 Calibration percent deviation from applied load at full scale.

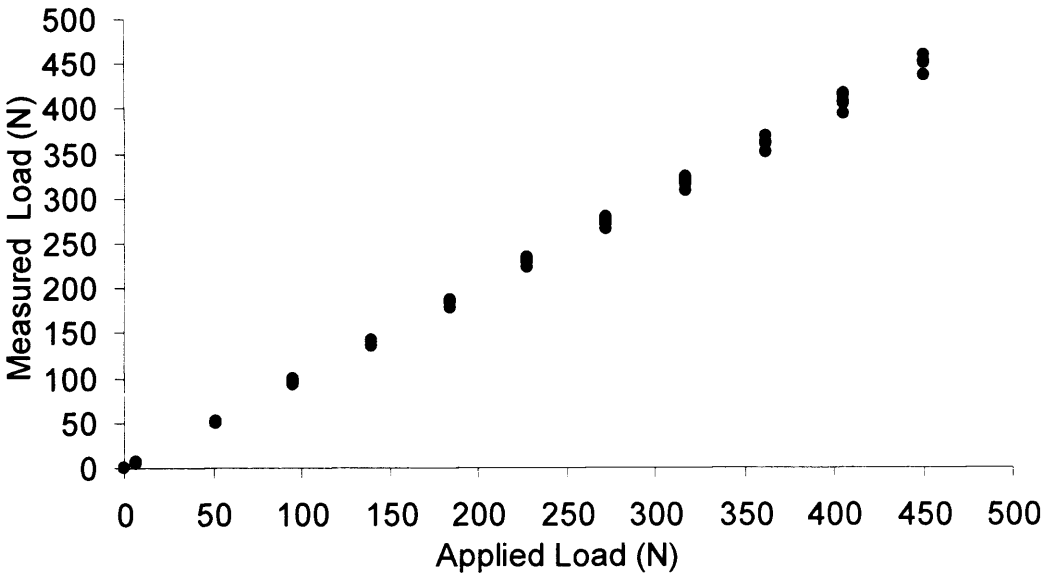


Figure 2.5 Expanding tool calibration performed on three different occasions.

2.3 Results

As shown in Table 2.1, there were 34 patients selected and overall 76 extension force measurements were made. Although collectively this is a substantial amount of information, none of the patients were measured from the first to the last extension sequentially. However, as shown in Figure 2.6 there were an adequate number of patients at each lengthening operation to provide a reasonable indication of the forces involved as an implant is extended. The first extension procedure was carried out between 8 and 34 months after the prostheses were inserted, with an average of 20 months, and the subsequent extensions were performed on average at 1.98 month intervals with each extension providing 6mm of growth.

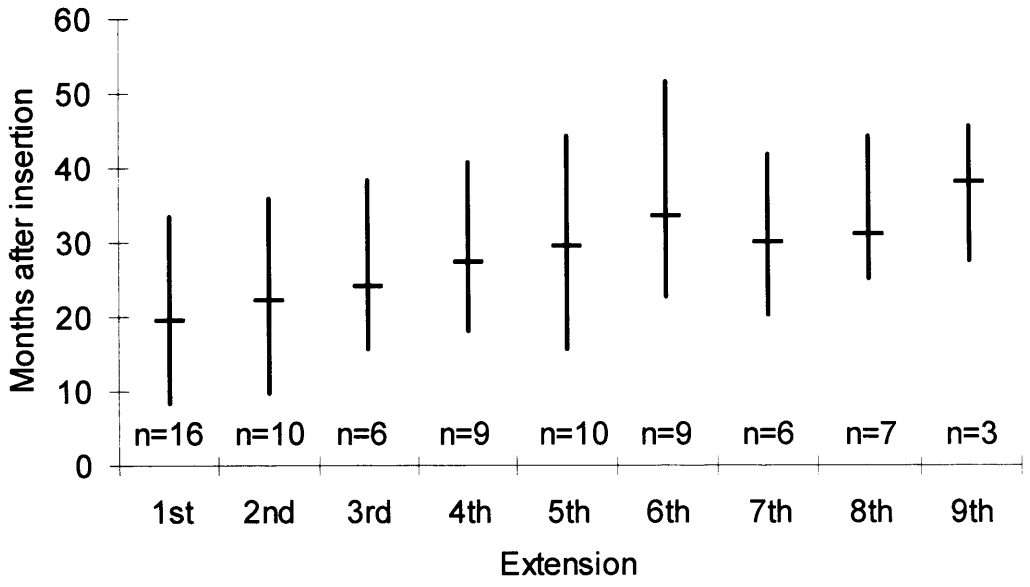


Figure 2.6 In the entire group of patients, first extension procedure was carried out between 8 and 34 months with an average of 20 months. The subsequent extensions were performed on average at every 1.98 months.

It is interesting to note that when age is assessed, it is usually assessed based on the time of implant insertion and not the time when the implant was extended. This is an important factor since the child grows, thus changing loading conditions. The age of the patient at the time of the lengthening operation should be considered. Therefore, in this cohort the patient age at the time of the lengthening operation ranged from 3.9 to 18.8 with an average

at 12.4 years, as seen in Figure 2.7. As there were children of all ages in this study, the only correlation one could evaluate is age at extension versus extension force, to see if the force changes with age. Two load conditions were examined: the preload on the implant prior to extension and the load at an extension of 6mm.

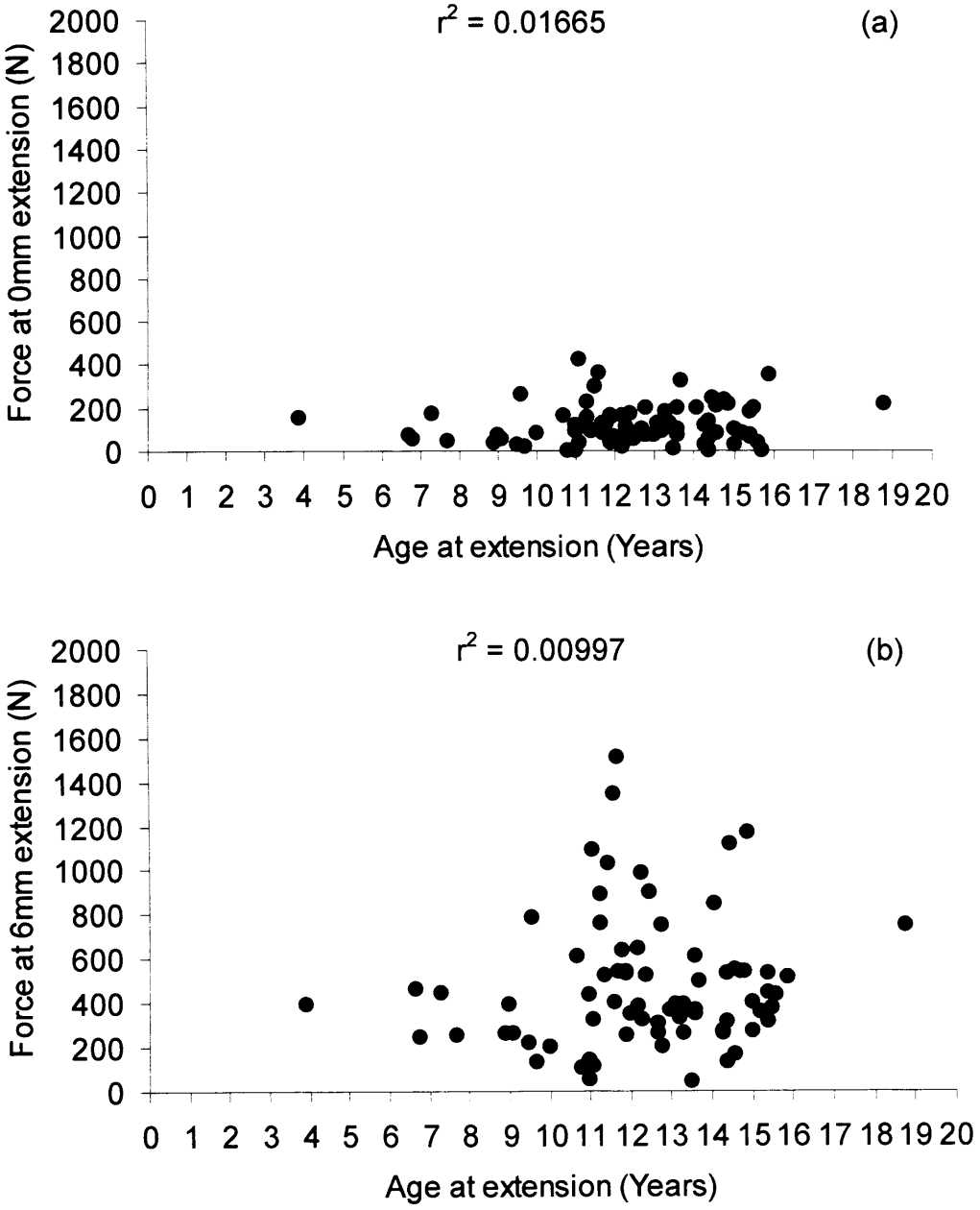


Figure 2.7 (a) Preload on the implant before extension,
(b) Load at 6mm of extension against age of patient at the time of extension.

The preload created by the soft tissues on the implant is shown in Figure 2.7(a) where the load is displayed against the age of the patient at the time of extension. The preload ranged from 1 to 422N with an average of 121N. The Pearson product moment correlation coefficient for this data was very small (r^2 = 0.01665), indicating there was no load correlation with age. Although it was predicted by regression analysis that there is a small increase with age (4.65N per year), this is insignificant and the scatter remains consistent with age. It is worth noting that the preload can be a major influence in some patients and it must not be ignored.

The peak load recorded at 6mm extension is shown in Figure 2.7(b). The peak load ranged from 42 to 1513N with an average of 479N. Here the force has increased substantially reaching almost 1600N. It was noted that at the time of lengthening, operation patients with a high distraction force had visibly large amounts of scar tissues present resisting the lengthening of the prostheses. The Pearson product moment correlation coefficient at 6mm extension was also small (r^2 = 0.00997), again indicating load did not correlate with age. There was small increase in load with age (12.05N per year) as predicted by regression analysis, but this is still insignificant in comparison with the peak load.

To assess the load as the implant is extended, force measured against amount of extension is shown in Figure 2.8. As one would expect, the forces in the humerus are comparable with those in the proximal tibia due to a distinct absence of large bending forces and small muscle volume in both bones. However, the femoral forces are much more prominent as a result of much larger muscle power and bending moments produced by offset load on the femoral head. Larger forces were recorded in the femur with noticeable differences between measurements and this is where largest preload of just less than 600N was recorded. From the results it was hypothesised that the bending moments applied on the prosthesis generate frictional losses in the telescoping metal parts during the lengthening process, contributing to the total force required to extend the prosthesis.

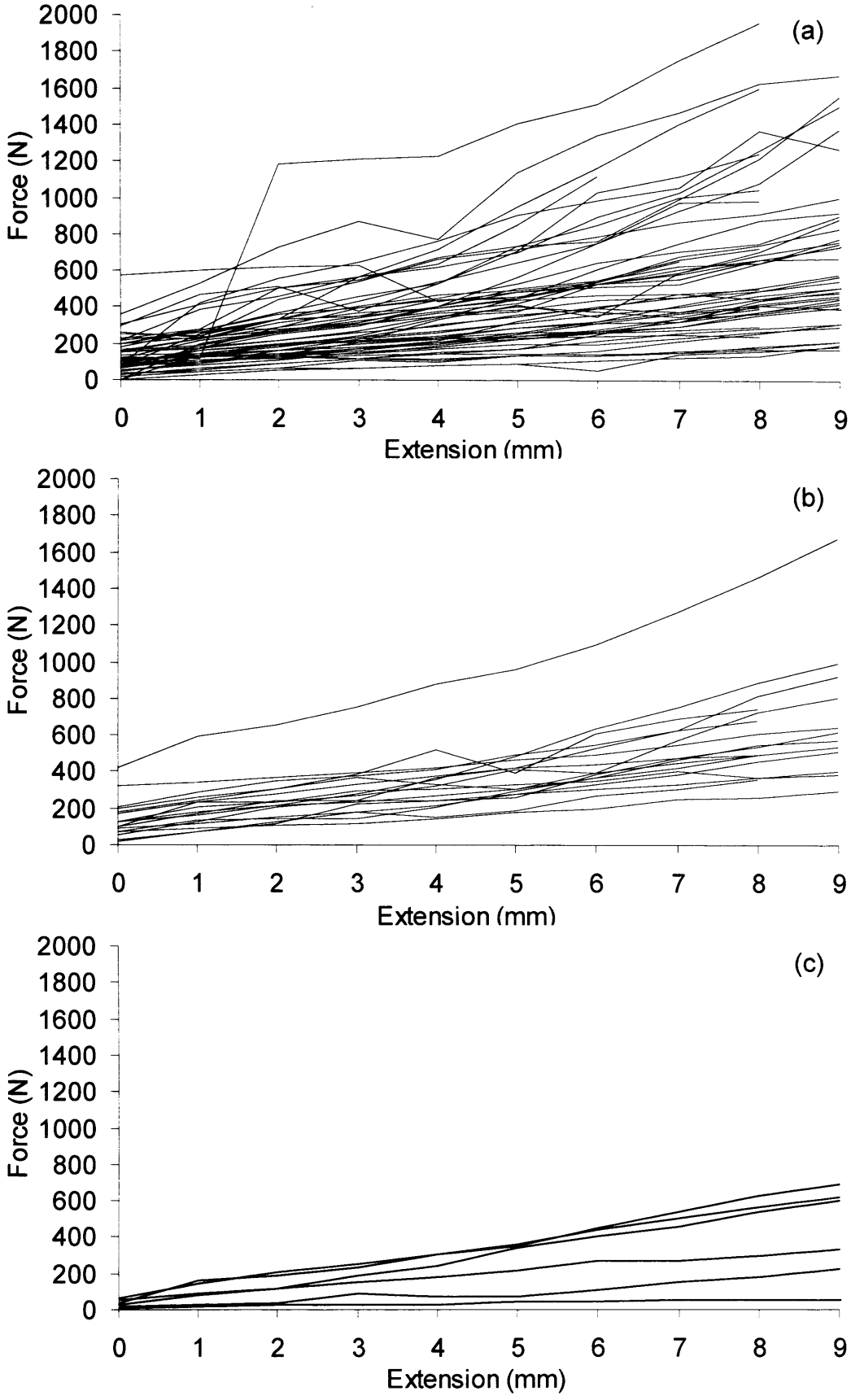


Figure 2.8 Forces recorded as the implants were extended in: (a) Femur (n=22), (b) Tibia (n=8), (c) Humerus (n=4).

2.4 Conclusions and comments

In conclusion, there is a significant amount of force carried by the prosthesis before any extension is carried out. This initial force can be as high as 600N and as the tissues became tensed in response to the extending procedure, the force increases almost linearly thereafter with increase in length. Therefore, a motorised device must be capable of starting from rest with an almost 600N load and then resist a rate of increase in load as predicted by the worst case in our series, which is approximately 175N per millimetre extension.

The study also suggests that the rate of increase in the limb is approximately 3mm per month and if the patients can be scheduled for monthly treatment then depending on the implant location in the body, i.e. upper or lower limb or distal femur or proximal tibia, the implant on average may only need approximately 3mm of growth per month.

A separate but related study was conducted by Williams *et al.* (2001) in an animal model where they distracted a limb at two different rates, 1.3 and 3.0mm per day, and examined the muscle damage and atrophy. They demonstrated that at the higher rate of distraction there was a significant loss of range of joint motion near the site of distraction and that there was increased fibre damage and atrophy. An important aspect of this study is that the authors have studied not just the physical fibre damage, but also the change in the expression of neonatal form of myosin which directly relates to the level of the regenerative process. It was found that at the higher rate the number of fibres expressing neonatal myosin was significantly reduced, indicating fibres were undergoing degeneration without subsequent regeneration and therefore reduction in muscle atrophy. Considering this factor, it is important not to over stretch soft tissues in the limb lengthening exercise. However, the study fails to establish the actual strain measured as a function of overall length against the amount of stretch in individual fibre groups, which is a true indicator of strain for comparison with various studies.

One further aspect of tissue stretching is to minimise the rate of expansion which allows time for fibres to recover whilst being stretched, either by plastic deformation or by breaking association with adjacent fibres. Although a crude measurement was performed in this study, the result is omitted and it is my recommendation that rate of recovery of fibres under tension is evaluated in the future.

The result presented in this chapter satisfies the project aim listed in paragraph 1.6, (A), (a) [Chapter 1, page 48]

CHAPTER 3

MOTION DESIGN

3.1 Introduction

In order to provide a controlled motion the skeleton consists of multiple segments joined together with ligaments and muscles. These segments, commonly referred to as bones, are components of the skeleton acting as beams, struts and columns experiencing various forms of loading and degenerative mechanisms. Coupled with this, there are bearing surfaces between the bones (joints) which allow articulated motion. The motions at the joints are controlled by the muscles and ligaments acting as linear actuators, operated at the molecular level by the cellular structure in response to the electrical signals received from the brain.

When part of a bone is replaced with an artificial joint, the components of the implant also experience similar loads and motions. Implants are also subjected to an aggressive environment. The only difference here is that there is no regenerative mechanism in the artificial implants to counteract the degenerative mechanism, which is usually in the form of fatigue and wear. Additionally, in children the skeletal growth that is present in the bones is not easily reproducible in artificial implants. The growth in the longitudinal direction of the bone is crucial in order to avoid limb length discrepancy which, if not maintained, is quite detrimental to the patient. Metallic implants are usually stronger in cross section compared with the equivalent bone section and hence they are capable of withstanding the fatigue loading. Fortunately, because the shaft of the prosthesis is relatively strong in cross section, it can be constructed such that it can be elongated to provide artificial growth to compensate for the lack of longitudinal growth. If anything, it is the fixation part of the prosthesis that is the weakest link and therefore it usually fails, as described in Chapter 1. There are a number of methods to address these issues.

It is the purpose of this research to evaluate design options for constructing a growing prosthesis and find an optimum solution by first looking at the prosthetic construct and then evaluating the drive mechanisms that can be accommodated within the confined space of the prosthesis. Having

established the prosthetic construct, it is also necessary to have an external drive that is easy to use and is precise in controlling the growth of the implant.

Design objectives:

In line with Chapters 1 and 2, the main objectives for the design are to:

(a) Evaluate the original implant design for performance and establish a baseline for further development by:
- Evaluating telescoping section to ensure adequate strength and defining strength characteristic for smaller sizes.
- Evaluating screw torque rating and the gearbox performance.

(b) Re-design the implant mechanism based on the performance obtained by:
- Reducing the size of the gearbox, both in terms of diameter and length, to establish miniaturisation. Current size being 18mm diameter by 19mm in length.
- Ensuring a load carrying capacity of 600N at start-up with 175N per mm growth thereafter, to a maximum of 1300N.

(c) Evaluate original coil design for performance and establish a baseline for further development and re-design the coil mechanism based on the performance obtained.

(d) Establish coupling characteristics of the implant/coil link for ease of use and consistent reproducibility.

3.2 Prosthetic construct

In a segmental replacement such as this, albeit in this case for children, the prosthesis must have a number of design properties. The main purpose of the implant is to replace the diseased bone as shown in Figure 3.1 and maintain a degree of mobility for the patient. A replacement prosthesis has a mid section acting as a spacer, usually referred to as the shaft of the prosthesis. In the case shown, the proximal end is fixated into the remaining

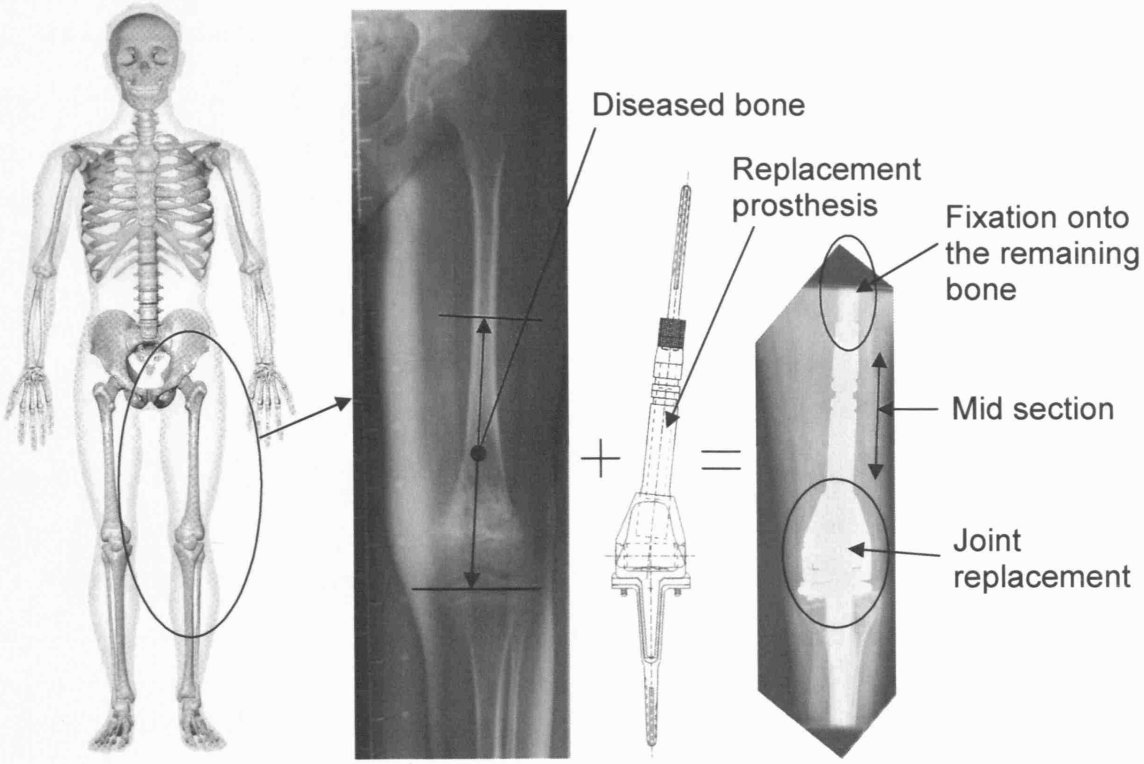


Figure 3.1 The main purpose of the implant is to replace the diseased bone.

segment of the bone where the fixation is usually intramedullary with a cemented or uncemented stem or extra-cortical with two or more plates attached to the bone with screws. A combination of a stem with plates is sometimes used. The other end of the shaft may have a similar arrangement or as in the case shown, a knee joint to articulate onto the adjoining bone. The type of joint used depends on the site and availability of a suitable joint

that provides good stability, compensating for any loss of muscles and other soft tissue support. Figure 3.2 shows different types of implants used in the lower limb. These are the most commonly used devices. Other less frequently used implants, such as in the humeral bone, are not shown but the principle remains the same. Joint design and fixation techniques are outside the scope of this thesis, but their selection has a profound effect on the construction of a growing prosthesis. Hence these features must be considered within the context of an extending prosthesis and how the whole construct could be made to best serve the patient.

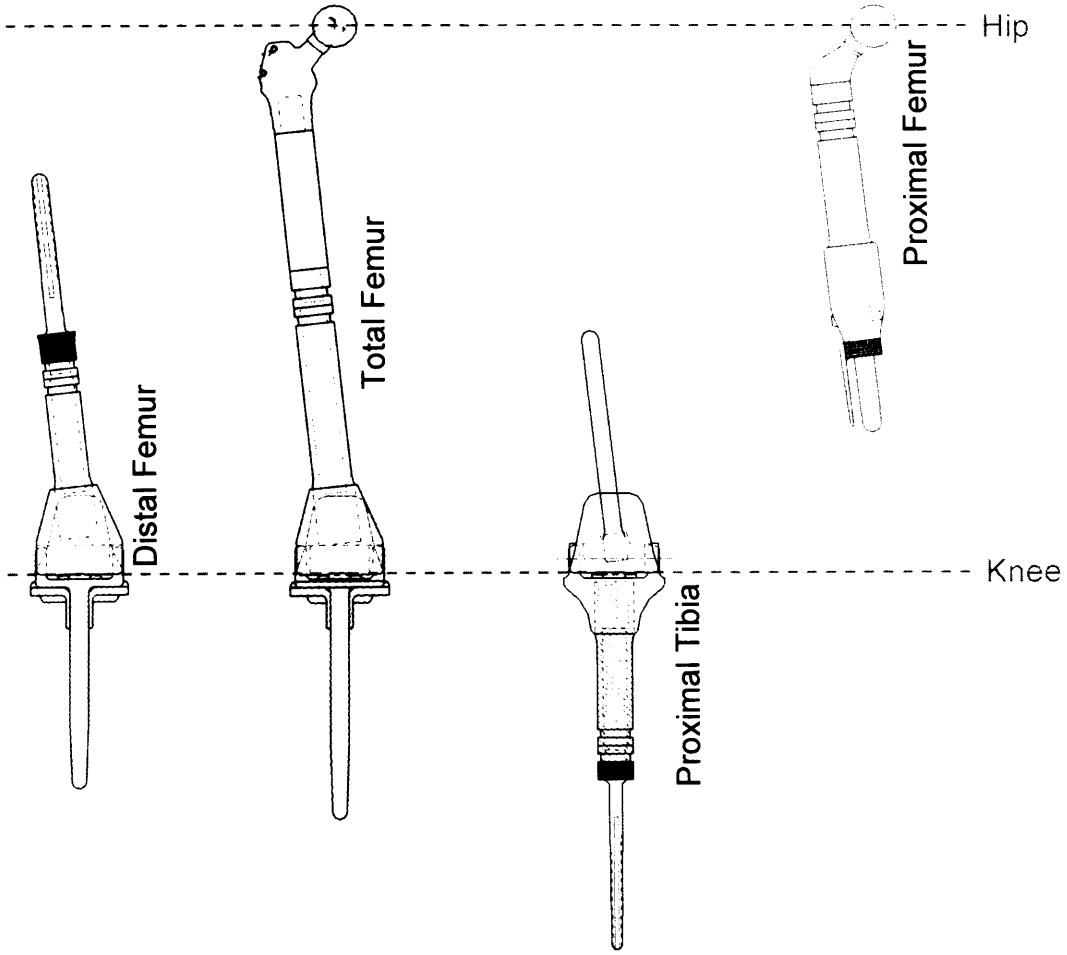


Figure 3.2 Implants in the lower limb.

There are hundreds of different types of standard implants available to orthopaedic surgeons for the treatment of joints, bone segments and/or the deficiencies in the surrounding soft tissues. These range from ligament

repair devices to complete bone replacement implants. Up to the last two to three decades, the majority of these devices were mono-block with options of a finite number of sizes for treatment of the majority of conditions. The tendency now is for devices to be modular in construction to treat a wider variety of different conditions and it is anticipated that there will be even further modularity and interchangeability over the next few decades. With the availability of modularity and a higher degree of interchangeability within a given system, a wider range of options becomes available for treating unconventional complications. This also makes it easier to change the construct should post operative complications occur, which is particularly important for implants that are well fitted and where there is no need to disrupt the fixation. This concept is also becoming apparent in the treatment of massive bone defects, where previously only customised solutions were used with very little surgical options. Modularity is an advantage for growing individuals where, either due to growth or to compromised fixation, parts of the prosthesis can be replaced.

The basic materials used have not changed very much and stainless steel, titanium and cobalt chromium molybdenum (CoCrMo) alloys, together with alumina ceramics and ultra-high molecular weight polyethylene (UHMWPE), are generally accepted materials. The alloying elements have changed a little, improving the material properties and there have been noticeable enhancements in manufacturing techniques. All of these factors contribute to stronger implants. What has made a big difference over the past few years is our understanding of how the body reacts to an implant and how it can be improved for longevity. Hydroxyapatite coating is used in combination with various designs to maximise the fixation, thus prolonging the life of the implant. Tissue engineering is also being used with implants to increase durability.

The growing prosthesis for young patients is an area where significant changes are required to improve the treatment. The following sections describe the evaluation and proposed solutions for better treatments for juvenile patients.

3.2.1 The fixation

Fixation is always difficult to achieve, particularly for immature patients. The intramedullary cavity in children is usually small and therefore the stem size used is controlled by the bone geometry. In a cemented stem, it is recommended that a 1mm polymethyl methacrylate (PMMA) cement mantle is used to provide an optimum thickness for the grout. A thinner cement mantle is likely to fragment due to bending and micro-motion between cement and the bone. On the other hand, thicker cement is mechanically not a problem but in practice, due to its exothermic reaction during the solidification process, the rise in temperature in the adjacent bone tissues causes them to die off. Therefore, too little as well as too much cement is detrimental. In general, a cemented stem is about 2mm smaller than the cavity and in small patients this may be a big disadvantage. In some patients, if the bone cortex is thick then the intramedullary cavity may be reamed to accommodate a bigger stem. However, this is usually not the case and clinicians strongly believe that it is not good practice to sacrifice good cortical bone by reaming. This is understandable since reinforced bone with a solid stem has reduced stresses caused by the shielding effect in the presence of a stem. Also, it is highly probable that the bone will lose its thickness with time. There are two problems here, as the patient grows the bone outgrows the stem size making it relatively weak and as the bone diameter increases it loosens the implant.

A stem under compression is usually strong, but bones are often eccentrically loaded causing bending and the bending stresses are often significant in comparison. This is a major issue in the lower limb and particularly in the femur where the load line is offset relative to the femoral diaphysis. It is in this bending mode that the stem usually fractures through fatigue.

To increase the stem section and hence reduce the likelihood of fatigue failure, uncemented fixation is recommended where the stem is made to fit the intramedullary cavity. As a rule of thumb, the intramedullary cavity is

reamed to provide at least 75% contact over its entire surface. The stem can be hydroxyapatite coated to encourage bone growth, increasing stem contact even further post-operatively and alleviating any concerns that the surgeon might have about reaming the bone to fit the stem. Mechanically, an uncemented stem has improved strength over a cemented stem by virtue of its increased stiffness, as indicated by equation 3.1. This shows the relationship between maximum stress and size of the stem in bending. The first part of the equation where σ is the stress in the metal, **r** is the radius from the centreline of the stem, **M** is the bending moment and **I** is the second moment of area of the stem section given by equation 3.2.

$$\frac{\sigma}{y} = \frac{M}{I} = \frac{E}{R} \qquad \textbf{Equation (3.1)}$$

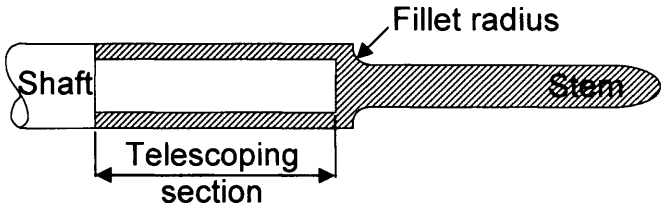
Where: $$I = \frac{\pi (r)^4}{4} \qquad \textbf{Equation (3.2)}$$

This implies that the maximum stress that occurs on the surface of the stem is inversely proportional to r^3. Therefore, a small increase in diameter has significant reduction in stress for a given loading condition. Therefore, an uncemented stem which is marginally bigger than a cemented stem for a given bone geometry should be more resistant to fatigue.

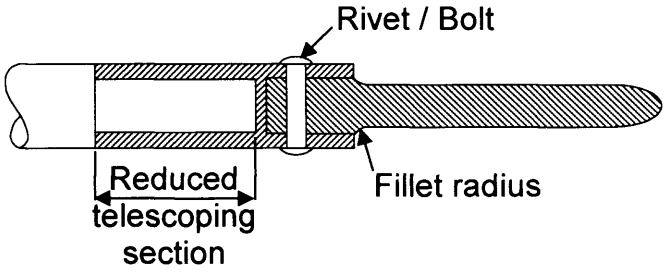
With extra-cortical plates however, the bending stress within the plates becomes much more critical since they are thin sectioned to allow flexibility and reduce stress shielding on the underlying bone. Also, the screws can fracture or loosen if they are unevenly loaded. For the plates to function properly, close contact against the bony surface is very important. It is worth noting that when properly fixed, plates do perform well. Coathup *et al.* (2000) produced a detailed study on the use of extra-cortical plates which supports this theory.

With all these designs, it is important not to stress shield the bone which eventually leads to bone resorption. Therefore, the fixation type must be chosen carefully when designing a prosthesis. The existing design concept

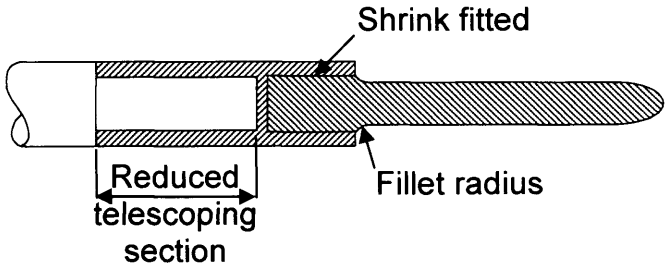
is to produce fixation features integral with the shaft by taking appropriate measurements from the scaled radiographs for optimum size. There are two ways to construct an implant with an integral intramedullary stem. A stem could be machined from a single piece of metal along with the shaft or it could be made separately and joined together by fabrication using bolts, rivets or shrink-fitting as shown in Figure 3.3.



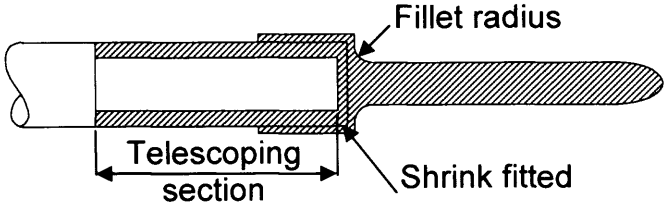
a) One piece construction with an integral stem for maximum growth.



b) Two piece construction with riveted/bolted stem with reduced growth.



c) Two piece construction with shrink fitted stem with reduced growth.



d) Two piece construction with shrink fitted stem with maximum growth but increased shaft diameter.

Figure 3.3 Stem / shaft construction.

One major disadvantage with a fabricated assembly is that it either dramatically reduces the length of the telescoping section that might be accommodated in a shaft as shown in (b) and (c) or increases the shaft diameter as shown in (d). For a modular system, the stem would probably be type (b) with bolts or without bolts with a tapered interface. One further aspect of stem design is the stress concentration effect at the base of the stem where it joins onto the shaft. A sharp corner has a high stress concentration effect, whilst a fillet radius reduces it. In fact the stress concentration effect is a factor of the degree of reduction in the section and the size of fillet radius. Therefore, the stress concentration in stem types (b) and (c) is much less than in types (a) and (d).

The extra-cortical plates are currently made integral. However, this technique does not allow any margin for error, particularly when the measurement radiographs are not always 100% reliable. A more adaptable approach would be to produce these features in a modular form so they could be selected inter-operatively for optimal fit but as explained above, the modularity would reduce the potential growth that can be accommodated in the prosthesis.

So, in general, the shaft may have a stem attachment on both ends or it may have a joint or an extension shaft attached at one or both ends. In the case of riveted, bolted or shrink-fitted assemblies, this would reduce even further the amount of extension that can be accommodated in the mid section of the shaft. One piece construction inclusive of a joint, on the other hand, is not often possible because of the complex loads and geometry. These joints require good bearing compatibility for the joint surfaces, which are usually made of CoCrMo alloy with UHMWPE. This bearing combination is used for many years with a typical wear rate of polyethylene in combination with a 28mm CoCrMo femoral head is in the region of 0.1mm per year as reported in numerous papers. For other joints such as the knee where the surfaces are non-conforming the wear rate can be much higher. One piece construction is only possible in the shoulder, where the requirement is usually a hemi arthroplasty, or the elbow joint, where loads are small and the joint

can be constructed using titanium for ease of manufacture. In the case of a distal femoral, total femoral and proximal tibial replacement, a knee joint made from CoCrMo alloy needs to be attached. For a proximal femoral replacement, an extension shaft with fixation device needs attaching as can be seen in Figure 3.2 where shrink-fitting over the shaft is the only option.

As mentioned in Chapter 1, it is very important to construct prostheses with maximum growth potential, particularly for very young patients and patients with a very short resection. Therefore, it is important to choose the correct type stem for each patient without compromising the growth. To the same extent it is desirable to have a modular construction so that the growth element of the prosthesis can be surgically replaced when it is fully extended without affecting the fixation.

3.2.2 The shaft

In order to lengthen the shaft it needs to be made in two parts that can telescope relative to each other providing length adjustment as shown in Figure 3.4. This is the simplest and most effective means of providing adjustable length. With any design the relative sections must be strong and stable over the entire growth range and at the same time be able to withstand daily load cycles in between the extension procedures. Without growing

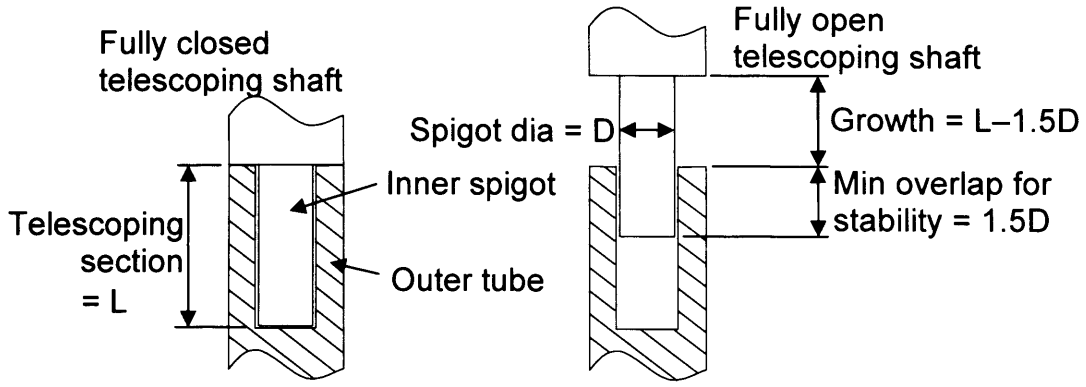


Figure 3.4 The basic principle behind telescoping shaft.

extra implant material in the patient, there is no other way to make the implant longer. The telescoping section shown in Figure 3.4 can be lengthened using a number of different methods such as collars, jacking screw, ball bearings, expanding spring, hydraulics and pneumatics as described in Chapter 1. No matter what the drive mechanism, the telescoping section when fully extended must be stable to withstand the loading. Therefore, as a general rule of thumb, the maximum amount of extension that can be achieved from a given telescoping section is limited to the length **L** less one and half times the diameter **D** of the spigot for stability when fully extended. The temptation here is to reduce **D** to maximise the growth potential. The maximum stress in the spigot is given by the equation 3.3 where **W** is the axial load on the implant, **A** is the sectional area, **r** is the radius, **M** is the bending moment and **I** is the second moment of area. The first part of the equation represents direct stress and the second part the

bending stress in the spigot section. In this application the direct stress is compressive hence it is negative. Also, a fracture usually occurs on the surface that is under tension.

$$\sigma_{max} = \frac{W}{A} \pm \frac{rM}{I} \qquad \textbf{Equation (3.3)}$$

When treating bone tumour, patient selection is not an option and the patient age, height, weight and tumour location is variable. Also, once an implant is successfully inserted, the patient may grow in stature and weight and therefore at the time of insertion the telescoping section must be maximised for strength. Taking an adult of average body weight (70kg) who has a tumour in the lower thigh, where compressive and bending forces are high due to preservation of a fully functioning proximal femoral section, maximum tensile stresses in the spigot can be predicted and a safety factor defined. Figure 3.5 shows safety factors for different size spigots in fully extended positions where the load is offset by 35mm. The solid line represents a solid spigot and the dotted line represents a spigot with an 8mm screw hole for the drive mechanism, as described later in this Chapter. In this case, the implant is made from titanium alloy and has a fatigue limit of 550 MPa. In order to provide a reasonable safety margin, say a factor of 2, the spigot must be

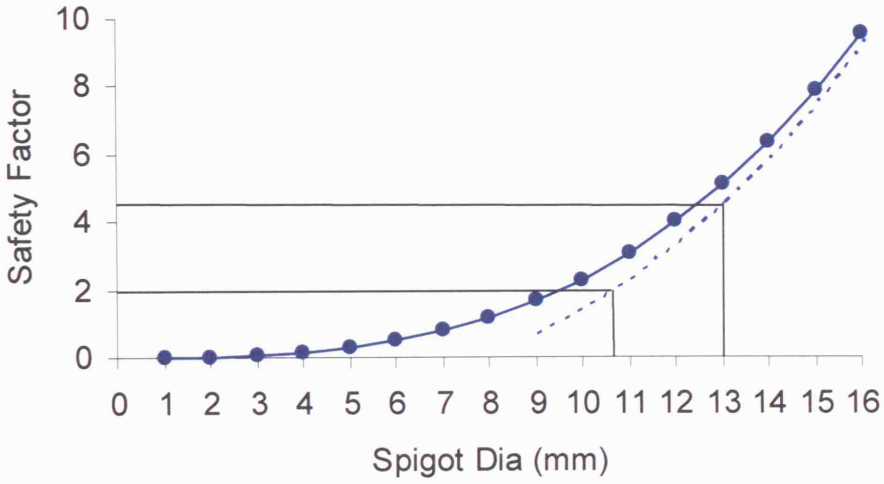


Figure 3.5 Increase in safety factor as spigot diameter is increased. Solid line represents solid spigot and the dotted line represents spigot with an 8mm screw hole.

bigger than 10mm in diameter for solid and 11mm in diameter for hollow sections.

Any additional features, such as a key way and small fillet radius at the top of the spigot, would necessitate a bigger spigot to provide the same degree of safety margin. This effect is evident in the clinical review for the spigot performance outlined in Chapter 4, section 4.2, where three 13mm spigots had fractured which, according to the above analysis, has a safety factor of 4.5. This emphasizes that a safety factor 5 or more must be used for the implant to cater for all patients.

3.2.3 Drive screw

In order to expand the telescope section and then maintain the prosthesis in an extended position with rigidity and allow further expansion on demand, the only mechanism that has proved clinically successful is the screw mechanism used in the minimally invasive device. Figure 3.6 shows schematics of the telescoping section with applied loads. The load **W** is

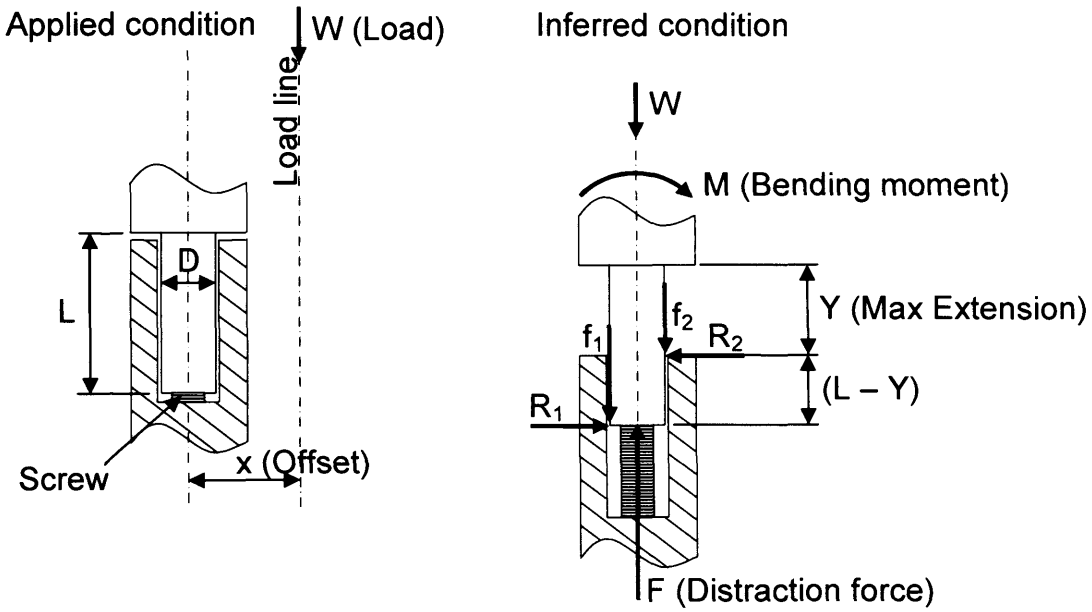


Figure 3.6 Load carried by the screw.

taken for a worst possible situation, as in the femur, but in this case it is caused by the soft tissue tension during the lengthening procedure, as described in Chapter 2, which induces a bending moment **M**. In Chapter 2 it was also hypothesised that the bending moments applied on the prosthesis generate frictional losses in the telescoping metal parts during the lengthening process, contributing to the total force required to extend the prosthesis. Thus the bending moment **M** is balanced by the reaction forces $\mathbf{R_1}$ and $\mathbf{R_2}$. By taking moments about $\mathbf{R_2}$:

$$M = R_1 (L - Y)$$

But $M = W x$

$$\text{Hence } R_1 = \frac{W x}{(L - Y)} \qquad \textbf{Equation (3.4)}$$

For equilibrium to exist:

$$R_1 = R_2 \qquad \textbf{Equation (3.5)}$$

Frictional force generated by $\mathbf{R_1}$ between the two telescoping components can be derived as follows:

$f_1 = \mu R_1$ Where μ is co-efficient of friction

By substituting equation 3.4:

$$f_1 = \mu \frac{W x}{(L - Y)} \qquad \textbf{Equation (3.6)}$$

From equations 3.5:

$$f_1 = f_2 \qquad \textbf{Equation (3.7)}$$

Therefore, total force carried by the screw is derived from summation of vertical forces:

$$F = W + f_1 + f_2$$

By substituting equations 3.6 and 3.7:

$$F = W + 2 \mu \frac{W x}{(L - Y)}$$

$$F = W \left(1 + \frac{2 \mu x}{(L - Y)}\right) \qquad \textbf{Equation (3.8)}$$

Efficiency is given by: $\eta = \frac{W}{F} \times 100\ \%$

Hence: $$\eta = \frac{1}{\left(1 + \frac{2\mu x}{(L - Y)}\right)} \times 100\ \%$$ **Equation (3.9)**

Force **F** is already predicted by clinical measurements, as described in Chapter 2 where it was directly measured in patients undergoing extension procedures on collar type prostheses made from titanium alloy. A maximum residual force of 422N was recorded due to tight tissues at the start of extension procedure. At 6mm extension a peak load of 1513N was recorded. However, to understand the effect of sliding parts in relation to the growth in a titanium alloy telescoping shaft, an efficiency analysis given by equation 3.9 was carried out for three extension lengths and spigot diameters ranging from 10 to 16mm. The American Society for Metals (ASM) Handbook – volume 18: Friction, Lubrication, and Wear Technology, refers to flat-on-flat with 50% relative humidity static coefficient of friction as 0.55 for titanium on titanium surface. Since the published values vary from 0.1 to 0.9 and in the absence of the exact value for a lubricated surface, 0.4 was considered to be an appropriate estimate. Hence for the analysis, the load offset was at 35mm as in the previous section and the coefficient of friction was 0.4. The result shown in Figure 3.7 indicates that the efficiency drops as the telescoping section extends and the rate of change is quite significant as the section approaches maximum growth. The efficiency is therefore independent of the load, but it is inversely proportional to the offset load line as shown in Figure 3.8. The analysis also shows that there is no difference with respect to the length of the spigot and that an increase in spigot diameter has an influence by the simple fact that bigger diameters require longer overlap for stability.

To withstand daily loads, wear and fretting in the threaded section, it is necessary for the threads to be of an adequate strength. Again clinical experience gained from the minimally invasive extending prosthesis provides a good platform to start from. As explained in Chapter 1, the original concept with a screw mechanism had an all titanium construct which had a tendency

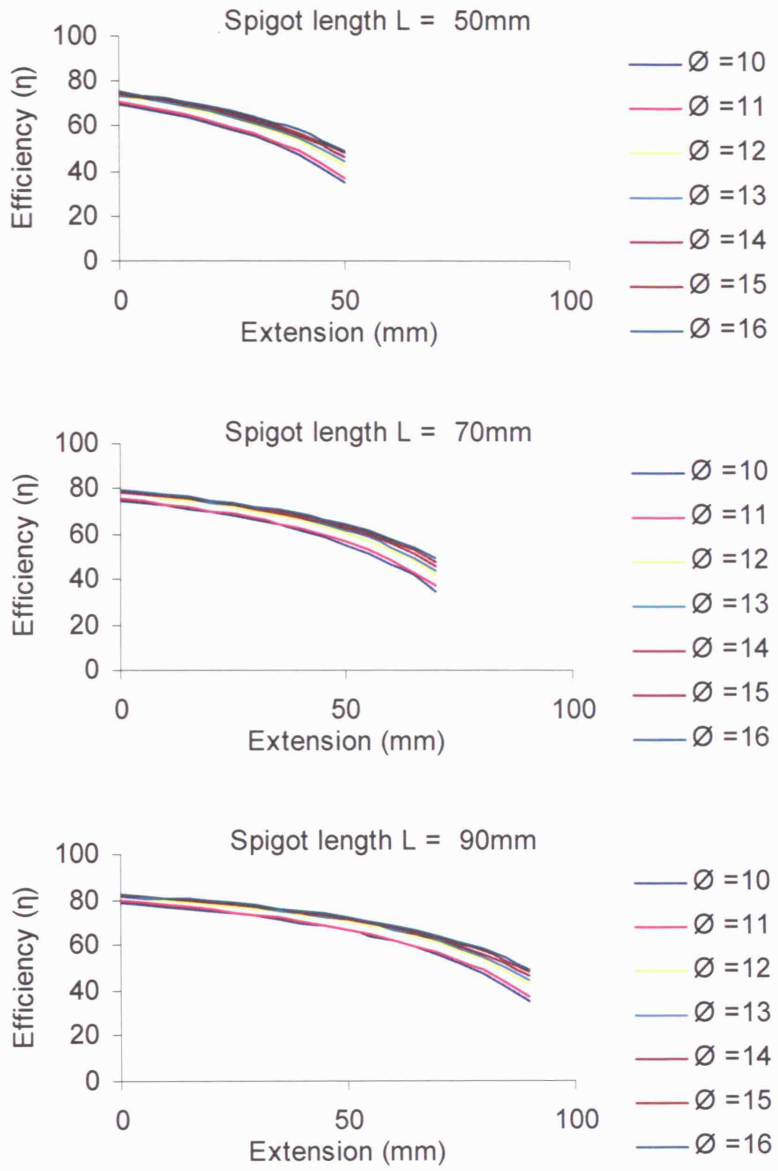


Figure 3.7 Efficiency of telescoping section for three length modules with spigot diameter ranging from 10 to 16mm and an offset load at 35mm from the implant axis.

towards cold welding and locking. For this reason a combination of metals was used in the minimally invasive device to reduce these problems. A titanium spigot with CoCrMo alloy provides much better bearing surfaces. An 8mm diameter CoCrMo alloy screw with 1mm pitch which was used in the minimally invasive implant has no reported complications relating to the thread form. To utilise a spigot diameter of 13mm, which falls within the criteria set out in Figure 3.4, a 7mm screw with 1mm pitch was chosen which increases the safety factor to 4.75.

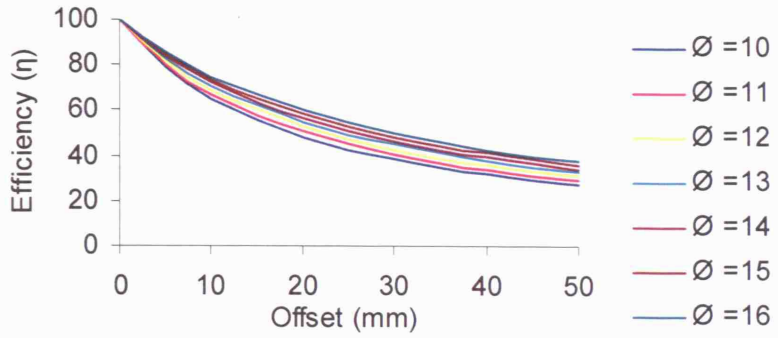


Figure 3.8 Telescoping section efficiency as a function of load offset.

As the screw is made to rotate, it lifts the load and in doing so it generates frictional losses at the screw / spigot interface on the threads and at the end where the thrust is exerted. As explained above the screw / spigot interface was chosen as CoCrMo alloy on titanium alloy whilst the thrust faces were CoCrMo on CoCrMo alloy to minimise wear and friction. Figure 3.9 shows the forces and the geometry at the contact surfaces. Frictional losses and consequential total torque required to drive the screw is well understood and the relationship is defined in the Mechanical Engineering Design – First Metric Edition, Pages 297-299 where, the total torque T_s to rotate the screw is given by:

$$T_s = \frac{F\, d_m}{2}\left(\frac{l + \pi\, \mu\, d_m\, \mathrm{Sec}\, \alpha}{\pi\, d_m - \mu\, l\, \mathrm{Sec}\, \alpha}\right) + \frac{F\, \mu_c\, d_c}{2} \qquad \textbf{Equation (3.10)}$$

Where;

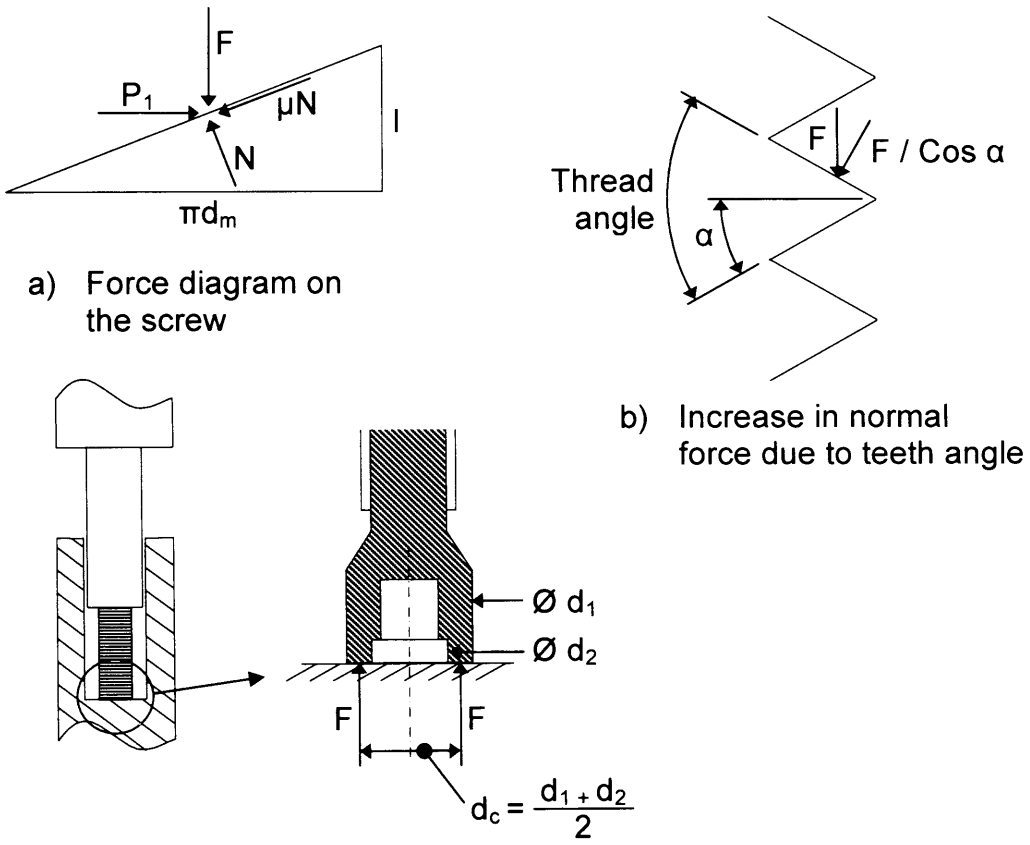
F	= Total load carried by the screw	= 1300 N
d_m	= Pitch circle diameter of the screw thread	= 6.35 mm
l	= Thread pitch	= 1.0 mm
μ	= Coefficient of friction at the screw threads	= 0.4
μ_c	= Coefficient of friction on the end thrust	= 0.4
d_c	= Mean diameter of the screw-end taking load	= 7.0 mm
π	= Pie	= π
α	= Half angle of screw thread	= 30°

The first part of the equation relates to the torque required between the screw threads and the second part relates to the load carried by the thrust face.

By substituting these values in equation 3.10:

$$\underline{T_s = 4.0 \text{ Nm}}$$

It is worth noting that the coefficient of friction of 0.4 is applied at both friction surfaces. In fact coefficient of friction between CoCrMo alloy surfaces should be well below that of titanium alloy surfaces. However, it is assumed to be the same to provide a conservative estimate.



a) Force diagram on the screw

b) Increase in normal force due to teeth angle

c) Reaction force acting at the trust face of the screw

Figure 3.9 Forces and geometry at the contact surfaces of the screw.

The screw can be driven in two ways: either by mounting the gearbox inside the screw itself, in which case a large screw diameter is required, or by mounting the gearbox at the thrust end of the screw, in which case another portion of the shaft length is taken, reducing the amount of growth that can be accommodated in the telescoping section. In the power screw, it is important to minimise the radial distance for thread contact where the friction occurs, whilst maintaining adequate structural strength so that the torque generated is minimised. So, there is a big disadvantage in increasing the screw diameter. A drive mechanism within the screw core was tried by Betz (European Patent number EP0959793, 1999-12-01) as described in Chapter 1, but has not proven successful. The only sensible position for the gearbox is below the screw. This technique provides a space for the gearbox that can be semi-sealed, protecting it from body fluids and isolating it when not in use, i.e. between the extension sessions. Figure 3.10 shows a typical section with drive in place. For a 13mm spigot the outer shaft diameter can be as small as 21mm, giving a 4mm wall thickness which is adequate for the telescoping section. To close the chamber a sealed screw cap is required.

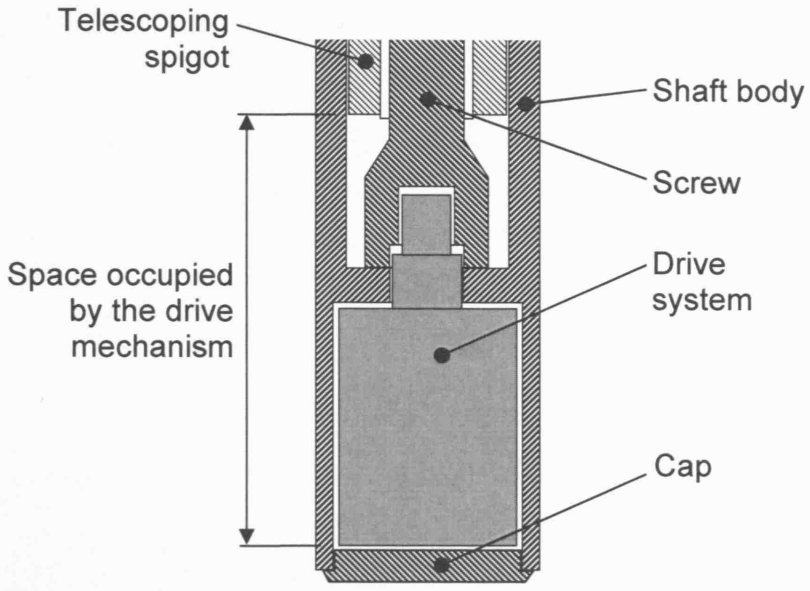


Figure 3.10 Position of drive unit in relation to the screw and the space occupied by it.

When an implant fails, the ability to replace just the damaged sections of the prosthesis is an important aspect of a good design. With the gearbox located under the screw there is an option to disengage the screw from the gearbox and retract it with the spigot, allowing it to be replaced.

3.3 Gearbox design and evolution

There are several types of gearbox configurations to provide torque or speed amplification or reduction. Spur gears are used for most systems with some variations, such as helical gears, to improve teeth contact and hence run much more smoothly, particularly at high speeds. Usually with simple spur gears the input/output shafts are unidirectional, i.e. they are in one line, but by using helical gears the output direction can be changed by up to 90°. Bevel gears are also used to change the direction of output shafts with improved efficiency. The complexity of the actual gear train depends on the application. Another concept for transmission is a worm drive, which is a two component system in which a gear is driven by a worm that looks like a screw. Although a worm drive with just two parts is very compact and can have a very high gear ratio, the power efficiency is not very high and the input/output shafts are at 90° to each other, making it difficult for some applications. Being a compact system a worm drive is used for the minimally invasive drive as described in Chapter 1, where as it is hand driven, the lack of efficiency has not been under question. There are other variations of the worm drive with slightly improved efficiency, but they all have a similar application. A novel idea developed some years ago by Walter Musser (US patent number 2930253) called a harmonic drive uses a rigid outer ring gear and a flexible inner ring gear. This is based on a simple spur teeth arrangement and the inner ring gear is distorted by a wave generator causing it to rotate. This drive has potential for a high reduction application in a confined space. The only limitations with this system are that miniaturisation at the level required in our application and adequate lubrication for the wave generator may not be possible. Therefore, this system may not be practical.

A two stage reduction gearbox based on the spur gear concept shown in Figure 3.11 was developed by Perry (1999), as part of his PhD study. The concept, in general, is extremely valuable since it provides a very high input/output speed ratio using spur gears in a small compact package similar to the harmonic drive. The differences between a conventional and this modified construction are shown in Figure 3.12.

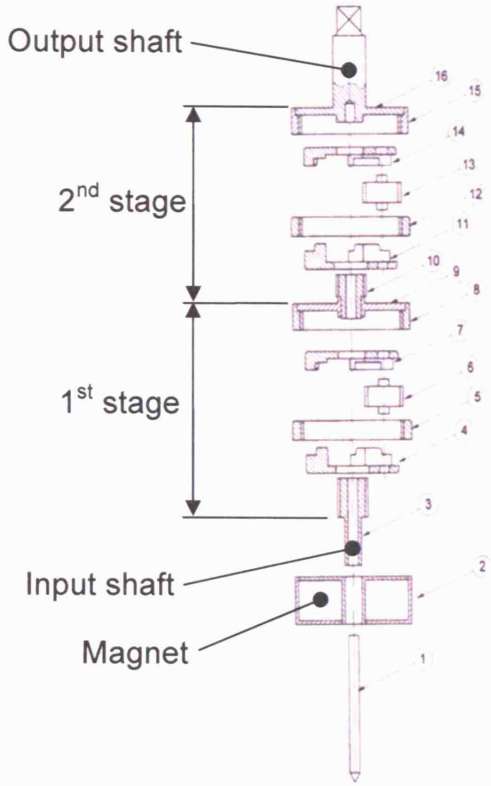
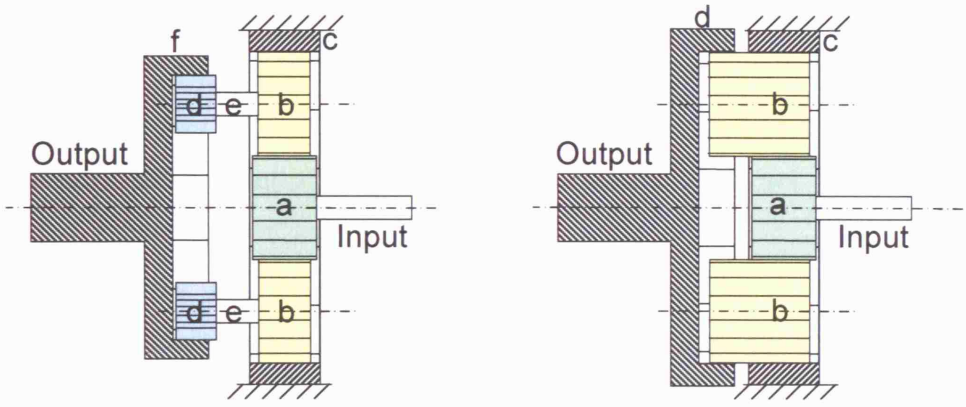


Figure 3.11 A compact gear train (Perry, 1999).



(a) Conventional gear train (b) Modified gear train

Figure 3.12 Difference between conventional and modified gear trains.

In a conventional gear train, shown in Figure 3.12 (a), the input is provided by the pinion **a** which rotates planet gears **b** within a stationary ring gear **c**, thus causing the planet gears to rotate within the ring gear. Since the second set of planet gears **d** are linked to **b** through a link shaft **e**, **d** rotates in synchronisation with **b**. In a real application, both sets of planet gears are mounted in a common cage (cage not shown here for simplicity) that is free to rotate around the input shaft. As the second set of planet gears rotate within the second ring gear **f** and because of differences between speed ratios of both ring sets, **f** rotates causing output shaft to rotate.

In the modified arrangement shown in Figure 3.12 (b), both ring gears are engaged with a common set of planet gears. Thus, in theory, both ring gears have the same number of teeth and this would result in zero output. However, if the second ring gear had one extra tooth, albeit with a slightly modified profile, then one full rotation of the planet carrier would cause the ring gear to inch forward by an equivalent to one tooth and conversely if the ring gear had one less tooth, then it would reverse the direction. In an ideal situation tooth shape is generated by involute profile and the tooth size is determined by the number of teeth and the teeth module, as described in the 26th Edition Machinery's Handbook, Table 1, Page 2004, which is a standard technique. There is a fixed relationship between the number of teeth, pitch circle diameter and the teeth module to provide smooth running and any deviation would result in excessive wear, weak profile and vibration. However, it was proven by a previous study that tooth profile is better if the number of teeth is reduced in this unconventional gear set.

Referring back to Figure 3.11, there are three planet gears in each set mounted in their respective carrier frames. The input pinion of the first stage is connected to a magnet providing propulsion for the system and the output shaft of the first stage is connected to the input pinion of the second stage, thus driving the second stage. Since both stages are identical, each providing 109.3:1 speed reduction, the overall reduction is 12037:1. For the teeth a 20° pressure angle and 0.2mm module was chosen based on the availability of manufacturing service at the time. 316L cold worked stainless

steel was chosen for all parts of the gearbox except the output shaft. This was made from CoCrMo alloy as this is the only part of the gearbox that was designed to protrude into the telescoping cavity where body fluids are present.

At this juncture it is important to consider galvanic corrosion which occurs when dissimilar materials are brought together in the body environment. Stainless steel has always been considered liable to corrode when coupled with either titanium or CoCrMo alloy. On the other hand, a titanium with CoCrMo alloy combination has successfully been used for many decades. However, a recent study published in the Journal of Spine by Serhan *et al.* (2004) suggests that there is a lesser concern of galvanic corrosion between stainless steel and titanium alloy than there is in a stainless steel construct. Several years earlier Kummer *et al.* (1983) also implied that titanium with stainless steel may be acceptable, whilst CoCrMo alloy with stainless steel is, without a doubt, not a good combination. Although, these studies are suggesting that titanium with stainless steel combination is acceptable there is not enough published evidence to give us confidence to use this combination. Therefore, it was decided to only use the combination we have always used. In the construction of this prosthesis it is thus important to isolate stainless steel components from the rest of the prosthesis, which is made out of titanium and CoCrMo alloy.

3.3.1 Gearbox evaluation

To assess the capability of this original gearbox, a series of tests and calculations were performed to examine if the gearbox was strong enough to carry the torque predicted by equation 3.10 shown in section 3.2.3. Closer examination of the gearbox suggested that, as both reduction stages are constructed using the same gear sequence, only the second stage is likely to have any strength issues. As described above, the output gear carries 4Nm torque and the components of the gearbox are made from 316L stainless steel, the material properties of which are shown in Table 3.1.

Tensile Strength Minimum		485 MPa
0.2% Proof Strength Minimum		170 MPa
Elongation		40 %
Hardness	Rockwell B	95 HR B
	Brinell	217 HB

Table 3.1 Mechanical property of 316L stainless steel.
(Specifications from Amari Metals Limited, UK)

The stresses in gear teeth under normal operating conditions can be predicted using a simple cantilever beam theory shown in figure 3.13. This was originally devised by Wilfred Lewis in 1893 and later modified by American Gear Manufacturers Association (AGMA) as reported by Vanderplaats *et al.* (1998), and is as follows:

$$\sigma = \frac{W_t}{K_v F m J} K_a K_s K_m \qquad \textbf{Equation 3.11}$$

Where, $W_t = \frac{2 T_s}{3 PCD}$ (Tangential force on tooth per planet gear)

F = Tooth face width (contact length taken from drawing specifications)

m = Teeth module

K_a = Application factor which is a probability factor for actual load to exceed the design load. To assess the design this is taken as 1.

K_s = Size factor which is for unusually big size gears and in our case it is 1.

K_m = Load distribution factor which accounts for inaccuracies in construction of gearbox. Again, to assess the design this is taken as 1.

K_v = Dynamic factor which is for large fast moving gears and is taken as 1.

J = Geometry factor which includes stress concentration effect and is taken from Table 13-4 Mechanical Engineering Design – First Metric Edition, Page 497.

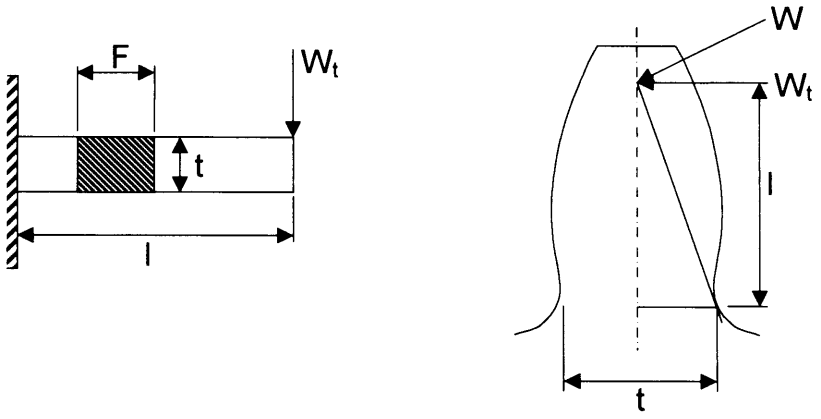


Figure 3.13 Loading on teeth as compared with cantilever beam.

The result of the calculations for the last two gears is shown in Table 3.2. These are rotating ring gears carrying the output shaft and the planet gear, both having a common contact face. The factor of safety for strength SF_s for these gears is quite clearly suggesting that the strength in the gear train is not enough to support the predicted torque. Furthermore it is quite possible, in a complex gear train such as this, for other gears in the system to fall below this level of safety. Therefore, a more detailed study was undertaken in collaboration with Davall Gear, Division of ITW Ltd, Welham Green, Hatfield, Hertfordshire, UK, using dedicated dynamic computation to assess the strength of all gears in the system. For the analysis, the following assumptions were made:

- The input speed was taken as 3000 rpm.
- All corrections for reduced number of teeth were applied to the rotating ring gear only.
- Light lubrication was used.
- Life of 100 hours was expected.

	PCD	N	Face contact	W_t	m	J	App Stress	SF_s
Planet gear	(5.4)	27	1.475	177.8	0.2	0.39964	1508	**0.11**
Ring gear	15.0	(75)	1.475	177.8	0.2	0.44418	1357	**0.13**

Table 3.2 The strength safety factor SF_s calculated for the last two gears by taking the ratio of yield stress *v* applied stress.

The strength and wear of the teeth were evaluated and the results are shown in Table 3.3. This method has predicted the stress safety factor for the rotating ring gear to be significantly higher than that predicted by the AGMA equation. This is because reducing the number of teeth by three in the ring gear with a set module of 0.2mm has made the teeth section thicker, allowing an increased load capability which the AGMA equation does not take into account. The result for the planet gear is however well agreed by both methods.

	1st stage		2nd stage	
	SF_s	SF wear	SF_s	SF wear
Sun Gear	19.57	**0.87**	3.54	**0.76**
Planet Gear (Fixed)	16.78	1.16	2.44	1.02
Fixed Ring Gear	23.30	1.82	4.47	1.31
Planet Gear (Rotating)	4.01	**0.93**	**0.15**	**0.30**
Rotating Ring Gear	7.80	1.40	**0.39**	**0.46**

Table 3.3 Safety factors for strength and wear for the original gearbox. (Supplied by Davall Gears Limited, UK.)

Although the wear safety factor is considered not so critical in our application because of a limited life span and a single unidirectional extension, it can not entirely be ignored. Deficiency in safety factors for both stages is quite apparent, falling well below a safety factor of one. There are a number of options to improve the safety factors and these are considered below.

Increase teeth contact:

As the stress is inversely proportional to the face width, the gear thickness can be increased. However, as previously discussed, space is an issue and realistically only a small increase can be accommodated. Furthermore, increase in width over and above a certain amount has negligible effect, mainly due to the inaccuracies and misalignments of teeth profiles. Although, a gear width over 10 times the module is considered inappropriate, for our application we should consider an increase of about 3mm. This amount will increase the safety factor approximately 3 fold.

Increase teeth module:

Increasing the teeth module from 0.2 to 0.25mm has a two fold effect: increasing the teeth section strengthens them against transmission force and increasing the gear diameter improves the mechanical advantage, reducing the torque required to operate it. Increasing the module to 0.25mm will result in an overall increase in diameter of 3.5 mm. This can improve the safety factor by about 60% which is not large, but is significant if combined with the increase in gear width as indicated above. Thus, an increase in safety factor can be almost 5 fold.

Improve material property:

The stainless steel 316L material used is relatively soft and being austenitic, heat-treatment has no effect. However, the material can be case hardened but this is considered not appropriate on the grounds that below a certain size, components do not easily lend themselves to post manufacture heat-treatment due to distortion and surface deterioration. In fact, it would not be possible to re-machine components after treatment and the distortion would be detrimental to the quality of the gearbox. Stainless steel 316L was chosen because neither titanium alloy nor CoCrMo alloy were considered stronger than stainless steel and both of these materials could have been problematic during manufacture and titanium could have impaired the performance due to poor friction characteristics.

One possible solution is to use a stronger grade of stainless steel. ISO 5832-9: 1992 "Implants for surgery – Metallic materials – Part 9: Wrought high nitrogen stainless steel" provides a much improved strength material and it is used in the manufacture of orthopaedic implants. The property of the material is shown in Table 3.4. This improved yield strength can increase the factor of safety by about 2.5 fold.

Tensile Strength Minimum	740 MPa
0.2% Proof Strength Minimum	430 MPa
Elongation	35 %

Table 3.4 Mechanical property of high nitrogen stainless steel bar <80Ø (ISO 5832-9:1992).

Moving away from orthopaedic materials, the only other option is to use marine metals such as super alloys which have superior strength, but still have anti-corrosion protection. One obvious material that comes from the marine application and which is high in strength is copper nickel MARINEL 220 alloy. The composition and mechanical properties are shown in Tables 3.5 and 3.6 respectively.

Element	Composition (Wt%)
Aluminium	1.6 – 2.2
Iron	0.65 – 0.85
Nickel	18.0 – 25.0
Manganese	4.0 – 5.6
Chromium	0.3 – 0.5
Niobium	0.55 – 0.9
Lead	0.02 Max
Tin	0.10 Max
Zinc	0.20 Max
Silicon	0.15 Max
Magnesium	0.05 Max
Sulphur	0.15 Max
Carbon	0.05 Max
Phosphorus	0.01 Max
Impurities	0.30 Max
Copper	Remainder

Table 3.5 Chemical composition of MARINEL 220 Copper Nickel alloy.

Tensile Strength Minimum		870 MPa
0.2% Proof Strength Minimum		700 MPa
Elongation		15 %
Hardness	Brinell	240 - 320 HB

Table 3.6 Mechanical property of MARINEL 220 Copper Nickel alloy. (Specifications from Amari Metals Limited, UK)

The problem with this material is that it is not tested for electron beam welding with CoCrMo alloy. Before we use this material we need to test the corrosive reaction as a gearbox inside the chamber. We also need to test the weld capability with CoCrMo alloy for the output shaft, followed by a test for corrosion reaction at the weld site over a long period.

Since the electron beam welded interface between stainless steel and CoCrMo alloy has been used, it makes sense to use higher carbon stainless steel to improve the strength, and only if this is not sufficient to then look at MARINEL. A commercially available corrosion resistant austenitic stainless steel (BS 2S 130: 1976) has 18% chromium and 9% nickel, is stabilised with niobium and is available in a heat-treated condition. This EN56AM grade has a yield strength of 540 MPa. Table 3.7 shows the effect of changing the material and some of the design parameters for the rotating ring gear for a comparative study.

In these calculations a true involute profile was assumed. In fact the output ring gear with a reduced number of teeth for the chosen module and diameter has a slightly modified tooth form. A repeat analysis using actual teeth geometry was done by Davall Gears (see Table 3.8). The result again shows a slightly stronger output gear than calculated. This is due to the thicker tooth section which AGMA calculation is not able to take into account. Although the output gear is now strengthened, the planet gear in the second stage falls below the required safety factor. The resultant damage is shown in Figure 3.14. To overcome this it was simply decided to reduce the rotating ring gear by 1mm and increase the fixed ring gear for the second stage by 1mm, thus improving the safety factor for the planet gear.

Option	Yield Strength (MPa)	PCD (mm)	No of teeth	Face contact	W_t (N)	Module (mm)	Lewis factor 'J'	Stress (MPa)	Strength SF_s
Original ring gear	**170**	**15.00**	**(75)**	**1.475**	**177.8**	**0.20**	**0.44418**	**1357**	**0.13**
Change module	170	18.75	(75)	1.475	177.8	**0.25**	0.44418	1085	0.16
Increase contact by 3 mm	170	15.00	(75)	**4.475**	177.8	0.20	0.44418	447	0.38
Increase contact by 5 mm	170	15.00	(75)	**6.475**	177.8	0.20	0.44418	309	0.55
Increase contact by 3mm for 0.25 module	170	18.75	(75)	**4.475**	177.8	**0.25**	0.44418	358	0.48
Increase contact by 5mm for 0.25 module	170	18.75	(75)	**6.475**	177.8	**0.25**	0.44418	247	0.69
Increase contact by 3mm for 0.25 module with high nitrogen SS	**430**	18.75	(75)	**4.475**	177.8	**0.25**	0.44418	358	1.20
Increase contact by 5mm for 0.25 module with high nitrogen SS	**430**	18.75	(75)	**6.475**	177.8	**0.25**	0.44418	247	1.74
Increase contact by 5mm for 0.25 module with high carbon SS	**540**	18.75	(75)	**6.475**	177.8	**0.25**	0.44418	247	2.18
Increase contact by 4mm for 0.25 module with high carbon SS	**540**	18.75	(75)	**5.475**	177.8	**0.25**	0.44418	292	1.85

Table 3.7 The safety factor for strength, SF_s calculated for the output ring gear with different module, face contact and yield stress.

	1st stage		2nd stage	
	SF_s	SF wear	SF_s	SF wear
Sun Gear	42.27	**0.89**	5.22	**0.69**
Planet Gear (Fixed)	18.94	1.16	3.11	0.90
Fixed Ring Gear	38.91	2.04	8.03	1.57
Planet Gear (Rotating)	5.41	**0.64**	**0.87**	**0.77**
Rotating Ring Gear	16.86	1.71	2.76	1.12

Table 3.8 Safety factors for strength and wear for all gears with the following parameters:

- EN56AM grade Austenitic Stainless Steel
- 0.25mm module
- 5mm longer output gear.

(Supplied by Davall Gears Limited, UK)

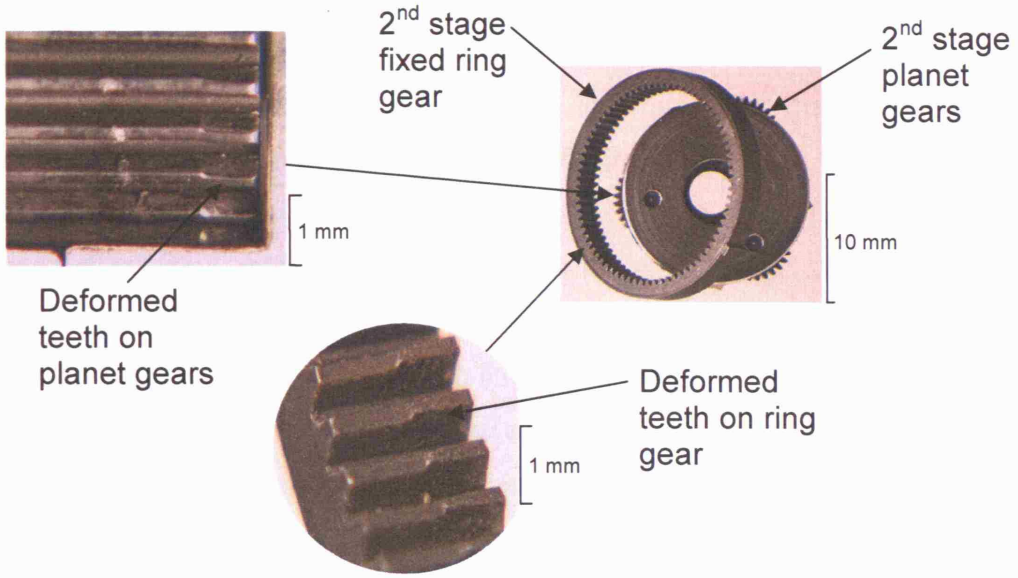


Figure 3.14 Teeth damage on 2nd stage planet and fixed ring gears. Teeth contact increased by 1mm which resolved the problem.

Now that the strength is within an acceptable range, there are still issues relating to the wear safety factor which remain almost unchanged because the bearing characteristics of the materials assessed have not changed.

Surface coating and lubrication:

The analysis conducted for strength also showed a prediction for wear loss in these gears. Even after introducing all the suggested modifications, the wear safety factor in the worst gear was still only 0.64. The wear characteristic can be improved by better lubrication, by treating the metal surfaces with a harder coating or by using a combination of the two.

The gearbox is sealed in a chamber with silicon O-rings which should prevent body fluid penetrating into the chamber and equally stop gearbox lubricant seeping out. As the shaft inside the O-rings is spinning, fluids from either side can lubricate the O-rings allowing small amounts of fluid to pass into the opposite side. Also, in the event of a major component failure the lubricant could contaminate the surrounding tissues which may have a detrimental effect. As there is the possibility for leakage of the gearbox, the lubricant used must be fully compatible with the body. Liquid paraffin has been used

orally, in wound dressings and as a lubricant for surgical instruments for many years. However, liquid paraffin was also used in large volumes for breast augmentation, directly injected into the mammary gland where it has produced an adverse reaction called paraffinoma. This was initially identified in the 1950's and has recently been reported by Ho *et al.* (2001) who have observed reaction after 11 to 30 years, with an average of 24 years in 8 patients followed over a period of 10 years. In our application, because of the small quantity (only a few micro litres) enclosed inside a chamber, it was considered safe to use paraffin as a lubricant for the gear mechanism. Anything else would require toxicity analysis prior to use and this is outside the scope of this research.

On a small scale, fluid drag and fluid surface tension become critical factors in generating resistive forces which would be detrimental to gearbox function and therefore low viscosity lubricants are the most suitable for this application. The use of liquid paraffin has the following advantages:

- It is readily available.
- It is used in surgery as a lubricant and is considered non-toxic.
- It would provide some lubrication reducing frictional losses as apposed to using a dry system.
- It has low viscosity which would create less fluid drag, particularly in the high speed gear set where the torque is very small.

One further consideration is the amount of fluid in the gearbox. The magnetic rotor should not have any peripheral fluid contact as the torque generated by the rotor is small and any fluid contact would make it impossible for it to start rotation. It is highly possible, due to prosthetic orientation, for the rotor to end up below the gearbox where excessive fluid could collect due to gravitational force. It is also true that by minimising the prosthetic size, there is minimal clearance between the rotor and the body of the prosthesis. Therefore, the lubricant must only lightly wet the bearing surfaces without running. It is possible that with time parts of the gear

mechanism may become relatively dry, so sole reliance on the lubricant cannot be accepted.

An alternative is to coat the gears with a harder coating that has a low coefficient of friction. BALINIT® C coatings supplied by Balzers Limited UK, is a tungsten carbide coating. This material was chosen for its high hardness and low coefficient of friction as shown in Table 3.9. Gear performance analysis with coating for the second stage is shown in Table 3.10. The analysis clearly shows that although the strength safety factor remains practically unchanged, the wear safety factor has significantly improved by the addition of the coating. With the additional change mentioned above for the 1mm increase in face contact for the second stage planet gears all, safety factors are now within the accepted range.

Coating Material	WC/C (a-C:H:W)
Micro-hardness* (HV 0.05)	1,500 / 1,000
Friction coefficient* against steel (dry)	0.1 - 0.2
Max. service temperature (°C)	300
Coating color	anthracite

Table 3.9 Properties of BALINIT® C coating.
(Supplied by Balzers Limited, UK)

	2^{nd} stage	
	SF_s	SF wear
Sun Gear	6.16	1.07
Planet Gear (Fixed)	3.15	1.44
Fixed Ring Gear	7.07	2.47
Planet Gear (Rotating)	**0.85**	1.23
Rotating Ring Gear	2.27	1.79

Table 3.10 Safety factors for strength and wear for all gears coated with BALINIT® C with the following parameters:
- EN56AM grade Austenitic Stainless Steel
- 0.25mm module
- 5mm longer output gear.

(Supplied by Davall Gears Limited, UK)

The final specification for the gearbox from the theoretical assessment is:

- Outside diameter — 21.5mm
  Resulted from an increase in;
  - Teeth module — 0.25mm
- Length of gearbox — 25mm
  Resulted from an increase in;
  - Output ring gear width — by 4 mm
  - Fixed ring gear width — by 1 mm
- Material — BS 2S 130: 1976 (1985) Austenitic Stainless Steel
- Coating — BALINIT® C
- Lubrication — Liquid Paraffin

It is worth noting that, as demonstrated in section 3.4 below, the performance of the new gearbox was smoother and predictable compared with the old gearbox. However, it must be emphasised that even with these improvements, the overall performance of the gearbox remains at the limits of the material property.

What is not easy to demonstrate without going into detailed analysis, is the frictional loss in the gear mechanism. The components of the gearbox were modified intuitively to minimise frictional losses between the adjacent contact surfaces.

3.3.2 Manufacturing process

Gears are machined with shaping or hobbing machines, either using form cutters or using hobbs to generate involute profiles. These machines are dedicated machines with cutters which are usually made from high speed tool steel or for difficult harder materials, from tungsten carbide. For high accuracy gears, after rough machining the teeth profile can be ground to size. These are standard techniques and there is no need to go into any more detail. It is the work holding that is of concern here. Harder materials require larger forces to cut and as the size gets smaller, the stresses due to cutting become significant. Also, the cutting action itself changes the surface stresses in the metal and for small sizes gears, particularly those with thin sections such as the ring gears, these stresses can become high and may be evident as distortion in the component. There was also concern that by choosing a harder material with a yield stress over 550 MPa, even carbide cutters would not suffice.

For this reason a different technique was required to machine the teeth accurately without causing distortion. A process called Electrical Discharge Machining (EDM) allows machining of hard materials that cannot be machined using conventional manufacturing processes. One advantage with this technique is that the material can be pre-heat-treated to optimise mechanical properties before machining the parts. As the process is non-contacting, the force exerted on the component can be extremely small making it ideal for very small delicate parts with miniature holding fixtures. Cutting is achieved by a stream of very fine sparks, creating very high temperature pulses emanating from the cutting tool and vaporising the surface of the adjacent metal work piece. The only requirement is that the metal must be electrically conductive for an electrical discharge to be generated across the gap filled with dielectric fluid. As the tool is sunk into the metal, sparks are produced across the shortest gap and thus an image of the tool is imprinted onto the metal by erosion as it progresses forward. This type of tool arrangement allows creation of a three dimensional surface identical to the tool geometry. Instead of a shaped tool, if a wire was pushed

through the metal sideways it would cut the piece in two like a wire cheese cutter. A wire EDM process allows complex shapes to be cut just like jigsaw puzzle pieces, by traversing across the work piece in an x-y plane. The wire diameter can be as small as 10μm for sheet sections up to 1mm usually used with micro-EDM machines and 0.1 to 0.5mm diameter for conventional EDM machines. To maintain the wire erosion to a minimum, the wire is drawn through the metal as it moves forward, thus fresh wire is always against the metal. Depending on the wire quality, speeds and metal being cut, this process can produce a superb surface finish requiring no further finishing operation.

To manufacture these small gears the choice of wire diameter depends on the size of the teeth, particular by the size of the fillet radius at the base of the tooth as shown in Figure 3.15.

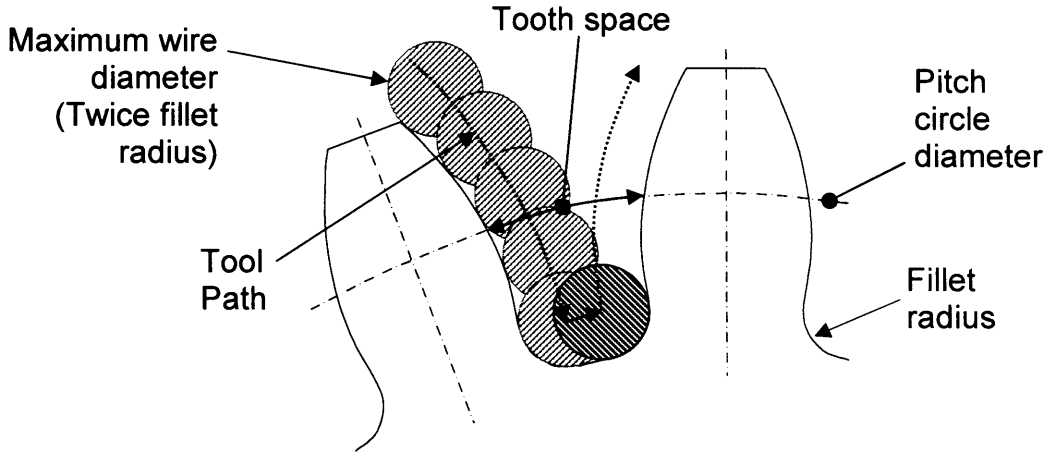


Figure 3.15 Maximum EDM wire diameter in relation to teeth size and its path as it traverses through the metal work piece.

For a 0.25mm module, the tooth space is 0.39mm and the fillet radius is about 0.1mm and therefore the ideal EDM wire size is 0.2mm. In this process wire feed, cutting feed and the wire tension are critical factors and if not controlled wire breakage becomes an issue, particularly with small diameters. With modern CNC machines these parameters are precisely controlled and this results in long operation times. However, it is quite possible to cut several components at once by stacking them together. Although, this increases the overall time it generally reduces time per

component. This is important as the manufacturing costs using this method are comparatively high.

The original gearbox made using conventional manufacturing techniques required a welded key as a separate production process to prevent rotation of the fixed ring gear inside the housing. As the size and depth of weld penetration is limited for such a small component, this assembly was not strong enough to support the required torque. With the EDM process the key was machined integral with the ring gear, thus strengthening the whole assembly.

3.3.3 Rotor encapsulation, chamber seal and gearbox assembly

As previously discussed, various parts of the drive mechanisms are made from different materials and therefore they are at risk of galvanic corrosion. These risks must be minimised for the device to function adequately over long periods and protect the patient from adverse effects. The main components of the gearbox are shown in Figure 3.16 and are listed in Table 3.11.

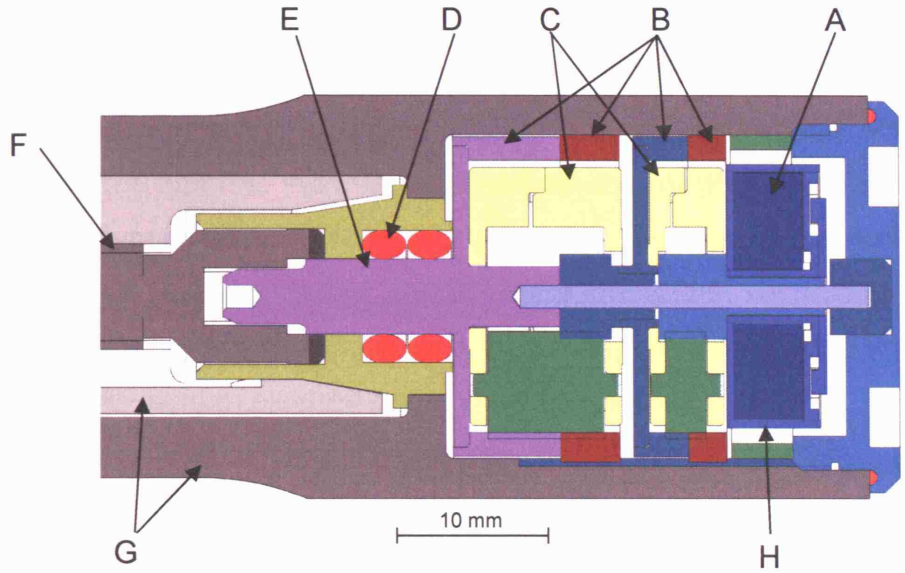


Figure 3.16 Components of the shaft as listed in Table 3.11.

Ref	Part	Material description
A	Rotor	This is a toroidal magnet made from niobium-iron-boron (NbFeB) rare earth magnetic material and is very corrosive in humid environment.
B	Gears	High strength EN56AM austenitic stainless steel
C	Planet carrier	Medical grade 316L stainless steel
D	O-ring seals	Medical grade silicone rubber
E	Output shaft	Medical grade cobalt chromium molybdenum alloy
F	Screw	Medical grade cobalt chromium molybdenum alloy
G	Shafts	Medical grade titanium 6Al4V alloy
H	Magnet casing	Medical grade titanium 6Al4V alloy
-	Coating	Components are Plasma tungsten carbide coated

Table 3.11 Components of the gearbox and the material used.

Encapsulation of magnet:

Ideally the magnet, being the most corrosive material in the system, should be hermetically sealed in a chamber. If corroded the magnet can lose magnetism and can easily fragment. Encapsulation was done by creating a titanium shell in two parts that can be welded together, trapping the magnet inside. Due to the limited space available, the casing was designed with only half a millimetre wall thickness. The magnet was made with a slot and one half of the casing was made with an integral ridge to locate inside the slot for rotational coupling.

The magnet required demagnetisation prior to welding as any magnetic interference from the magnet would deflect the electron beam away from the point of application. At this stage it was not clear how much residual magnetism would prevent welding and therefore demagnetisation was carried out repeatedly. Parts were then cleaned and assembled for welding using high vacuum electron beam welding equipment.

Several attempts were made to centralise the beam in a circular path, but it was observed that even a small amount of magnetic flux left in the magnet had a noticeable effect on the beam. However, the welding was completed as shown in Figure 3.17 and the component examined. In addition to the elliptical path, in one place, the weld had penetrated through the casing creating weld directly onto the magnet, exposing some of the magnet material. The welding process was not successful.

For completion of this exercise, the magnet was tested for strength before demagnetisation and again after re-magnetisation to see if there were any complications in obtaining pre-weld strength. The test was conducted by mounting the magnet in a holder as shown in Figure 3.18, allowing it to contact a steel plate and then pulling it using a Hounsfield extensometer at very low speed. Note that the magnet was encased in a titanium shell for this test. The pull-off strength recorded was 7.7N before demagnetisation and 8.0N after welding and re-magnetisation. The difference is well within the

variability of the magnetisation process (not tested nor verified in this instant). This attempt to hermetically seal the magnet was unsuccessful, and therefore, it was decided to glue the components together.

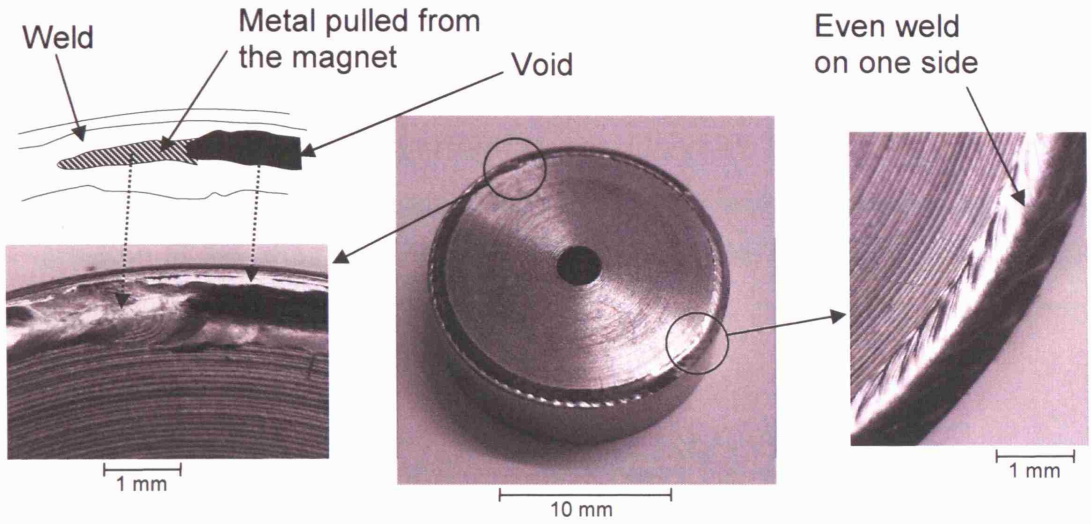


Figure 3.17 Welded joint on the casing containing the magnet. Weld penetrated down to the magnet exposing magnet metal on the surface.

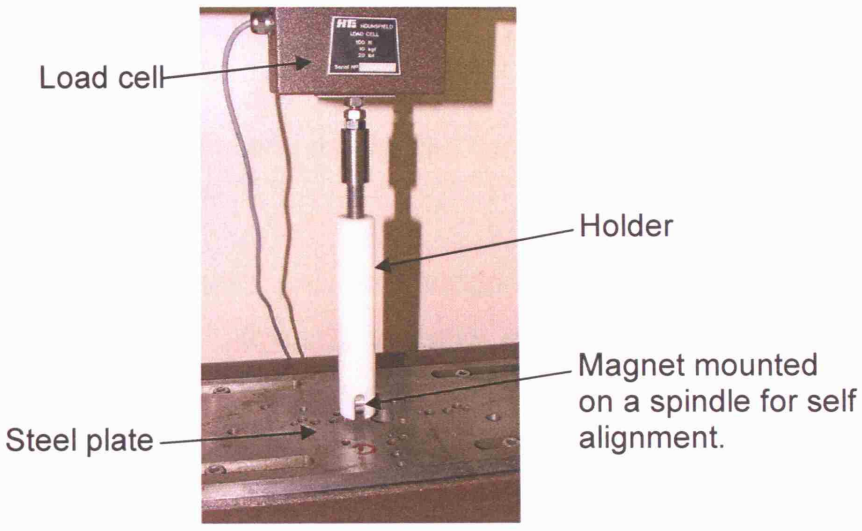


Figure 3.18 Experiment to measure magnetic field strength of a magnet encased and welded in a titanium shell.

Chamber seal:

The output shaft from the gearbox is designed to protrude into the telescoping section in order to engage onto the drive screw. The seal hosing is provided to accommodate a pair of silicone O-rings, where the performance of these seals was tested and the result presented in Chapter 4. Since the output drive speed is very slow and only turning to a maximum of 150 turns, this seal is considered adequate for the application. Having assembled the output seals and the gearbox with lubrication through the opening in the shaft, the cavity is then sealed with the end cap as shown in Figure 3.19.

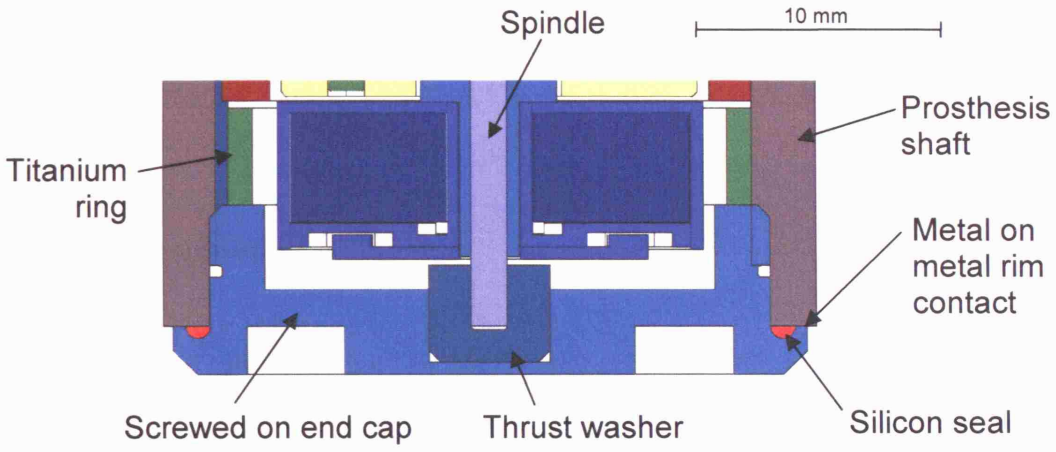


Figure 3.19 End cap seal and associated components.

The end cap has two functions: provide a support for the gearbox spindle and to provide a large enough opening to allow easy gearbox assembly. A welded cap would be better, but several complications were encountered. A welded cap can only be possible by using electron beam welding. The presence of a lubricant in the gearbox would not allow an adequate vacuum for the welding process. An alternative was to add the lubrication after the weld was done, in which case a small aperture was required on the side of the chamber to inject lubricant into the cavity. There were two main complications with this concept. A method could not be established to inject

just enough lubricant, wet all the bearing surfaces right down to the spindle and leave no excess lubricant, which could introduce enough drag on the magnet to prevent it from spinning. Secondly, there was the question of how best to seal the aperture. For these reasons this process was considered not appropriate. Instead, a screw cap with an O-ring was chosen which allows controlled assembly and an effective seal.

To ensure that the thin O-ring was correctly positioned during assembly it was placed in such a way that when the cap was screwed on, it squeezed the O-ring in place through compression. Therefore, the O-ring was set in a recess under the flange, allowing partial compression of the O-ring before the peripheral rim on the cap took the main thrust, as shown in Figure 3.19. The rim contact provided a primary seal whilst the O-ring acted as a secondary seal. One further requirement was that the shaft was then shrink fitted into another component, as shown in Figure 3.3(d), further enhancing the barrier against invasion from body fluid.

Gearbox assembly:

As discussed previously, the gears are made from EN56AM which is an austenitic stainless steel, but the material has some magnetic properties. The first stage planet and fixed ring gears, being the closest to the magnet, have a small affinity to get pulled against the rotating magnet, thus causing the magnet to stop or in some instances flutter. To overcome this, the fixed ring gear is held away from the magnet by a titanium ring (shown in Figure 3.19) inserted in between the fixed ring gear and the cap, with a small clearance so that the rotating components of the gearbox are not clamped. The planet gears are mounted in a cage made from truly non-magnetic 316L stainless steel, where the cage is kept away from the magnet by the pinion attached to the magnet. To provide this arrangement, the gearbox is assembled in situ to allow measurements to be taken to calculate titanium ring and thrust washer thicknesses and the length of spindle. These parts are then machined to provide 0.15 to 0.16mm overall clearance, assembled and the assembly tested with the cap fully tightened.

The cumulative effect of the manufacturing tolerances in these components can result in an overall tolerance of up to 2mm. To provide just enough clearance in the gearbox, the titanium ring, thrust washer and the spindle are designed to be trimmed to size. Having made the first assembly, these parts are separated, cleaned and reassembled in a clean environment and the assembly tested again. The functional test is repeated during various production stages to ensure no subsequent operations have any detrimental effect on the gearbox performance.

3.4 External drive design and evolution

In an electric inductive motor there is a stator, which is the outer part of the motor attached to the casing and a rotor, which is the central part of the motor and which is free to rotate about the long axis. The main purpose of the motor is to convert electrical energy into a rotary mechanical action as shown in Figure 3.20. The concept of AC and DC electrical motors is well understood and the purpose of this study is to utilise this concept in a slightly modified way to allow a remote extension in the prosthesis.

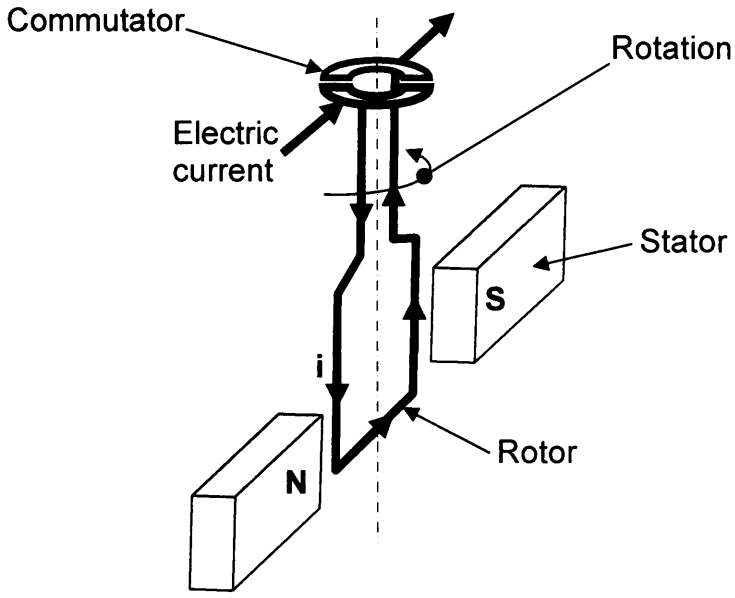


Figure 3.20 Basic principle of a DC electric motor.

In general a DC motor requires a commutator to switch DC current from one phase angle to a slightly advanced angle in order to produce a propulsion force to cause continuous rotary action in the rotor. Direct access to the rotor from the power source is essential for this type of DC motor. However, there is no reason why the stator itself could not be commutated in order to provide a rotating magnetic field whilst either utilising eddy currents or using a permanent magnet in the rotor core to cause a rotary reaction. This type of DC motor is usually referred to as a brushless DC motor, where commutating is done electronically. Equally, a single phase AC current could be used to

generate the same effect without having to use commutation and when a large amount of power is required, a three phase supply is used. There are two configurations of a three phase motor; star and delta configuration as shown in Figure 3.21. In a conventional electric motor the stator and the rotor are constructed to channel magnetic flux across the air gap, which is usually small for an optimum coupling torque.

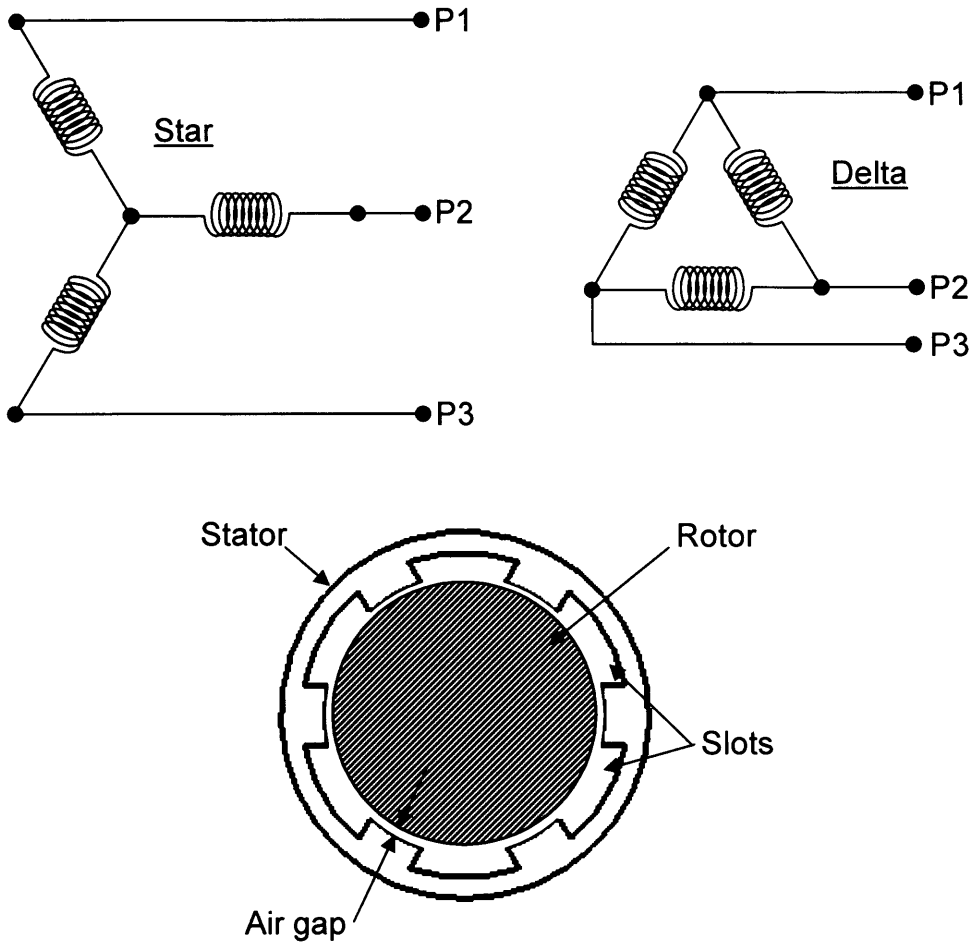


Figure 3.21 Three phase connections using Star and Delta configurations at the top and parts of the motor below.

Depending on the application, the coil can be wound to provide a multiple number of north and south poles. Figure 3.22 demonstrates how a rotor rotates as the three phases sweep through the cycle for a motor with a single pair of north and south poles, as in our application.

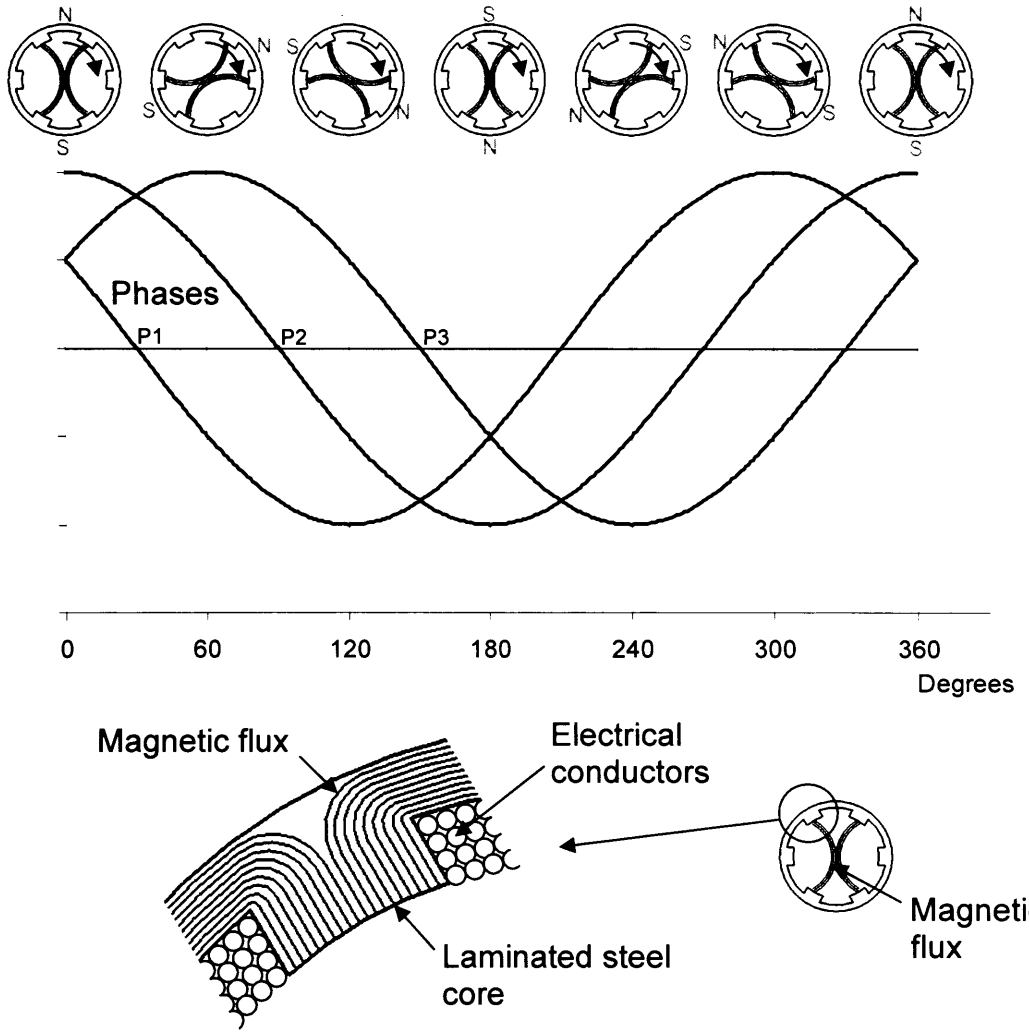


Figure 3.22 Magnetic flux rotates inside the stator as the three phases sweep through the cycle and a section showing how the flux is channelled through the laminates.

As a current is passed through a single conductor in air, a circular magnetic field is produced. More than one parallel conductor produces a cumulative effect, increasing the magnetic density. By using steel laminates in the coil, the flux is channelled through the laminates and is directed to optimise magnetic coupling between the stator and the rotor. An example of a laminated coil and the way the flux passes through the lamination is shown in Figure 3.22. The material for lamination has advanced significantly over the past few years, providing high anisotropic permeability designed to minimise flux losses, thus improving the efficiency of the device. Laminates are used for both stator and rotor depending on the design type.

3.4.1 Evaluation of existing external drive unit

The drive mechanism chosen for the extending growing prosthesis is like an electric inductive motor but with some major differences. The large stator stays outside the patient and generates a rotating magnetic field with one single pair of poles. The rotor on the other hand fits inside the prosthesis and is directly connected to the gearbox. As the space inside the prosthesis is very small, the rotor can only be in the form of a permanent magnetic disc with a diametrically orientated single pair of poles. The stator and the rotor are now two separate entities in two different environments and when placed coaxially, they are separated by a large air gap partially filled with body tissues and non-magnetic metallic parts of the prosthesis. The parts of the prosthesis and the body tissues are non-magnetic and play an insignificant part in the magnetic circuit. As the external drive unit is activated, it captures the poles of the magnet causing the magnet to rotate in synchronisation.

The Mk1 drive unit shown in Figure 3.23 was tested for performance. In this device the coil was mounted on a lever arm and was raised to limb level when required. The limb could be inserted from either side of the coil. Controls were very simple with a clockwise and counter-clockwise magnetic

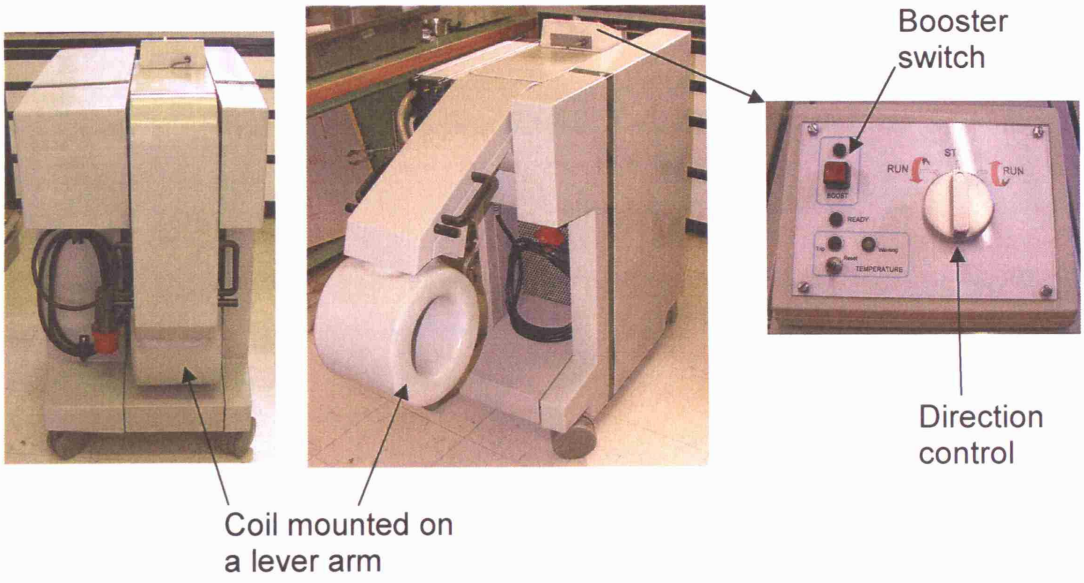


Figure 3.23 Mk 1 drive unit with adjustable arm and a booster control.

field rotation switch. A booster switch, when pressed, generated an increased coil power for approximately 2 seconds to kick-start the implant magnet. The unit required a few seconds to warm-up and circulate the fluid which was used as a coolant. The coil with a star configuration was energised from a three phase power source.

There were a number of concerns with this device. These were:

- Although mounted on wheels, the device was very heavy and was not easy to transport between different hospitals for lengthening sessions.

- Not all hospitals have a three phase electrical supply near to the outpatient department.

- The equipment caused interference to other electrical equipment nearby and hence isolated accommodation was necessary.

- With the cooling fan running, the device was very noisy and required several minutes after use for the coolant to return to room temperature before it could be switched off.

- It had a cooling oil reservoir that had to be topped-up on regular basis.

- Being a complex piece of equipment, regular maintenance and service was necessary.

The main elements of the system were evaluated in order to resolve these issues.

Cooling system:

The Mk1 coil was sealed in a glass-fibre body and filled with transformer oil, which was circulated by a hydraulic pump to maintain coil temperature just above room temperature. The oil cooling was achieved through a fan assisted heat exchanger, shown in Figure 3.24. There were numerous leakage problems, particularly from the fibreglass body around the coil which was very difficult to seal. It was decided either to find an alternative sealed chamber that was leak free or to use a dry system which did not require air cooling.

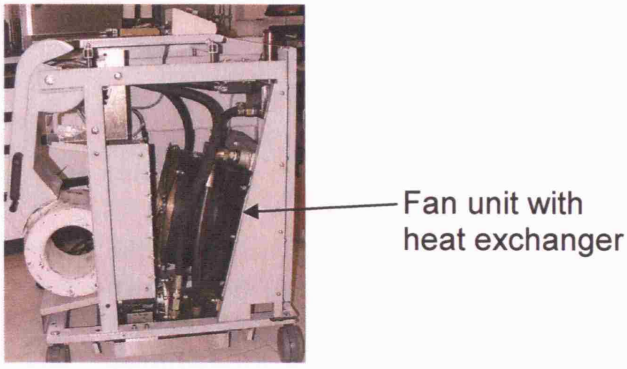


Figure 3.24 Hydraulic cooling system in Mk 1 drive unit.

The coil:

The coil was constructed using 0.8mm diameter copper conductor wound in six equi-spaced overlaying bundles, as shown in Figure 3.25. The conductors were then enclosed in a fibreglass casing filled with circulating transformer oil for cooling.

The coil construction allowed a magnetic flux to be generated which emanated in all directions (Perry, 1999) causing electrical interference to other nearby electrical equipment. Furthermore, due to loosely wound coils with conductors touching in places and large gaps in others, a variable field was generated with hot spots where the conductors were tightly bundled together. It was felt that reproduction of a similar coil would be very variable

and more importantly, containment of the magnetic field was necessary. However, as a starting point and to form a base line, the coil performance was tested.

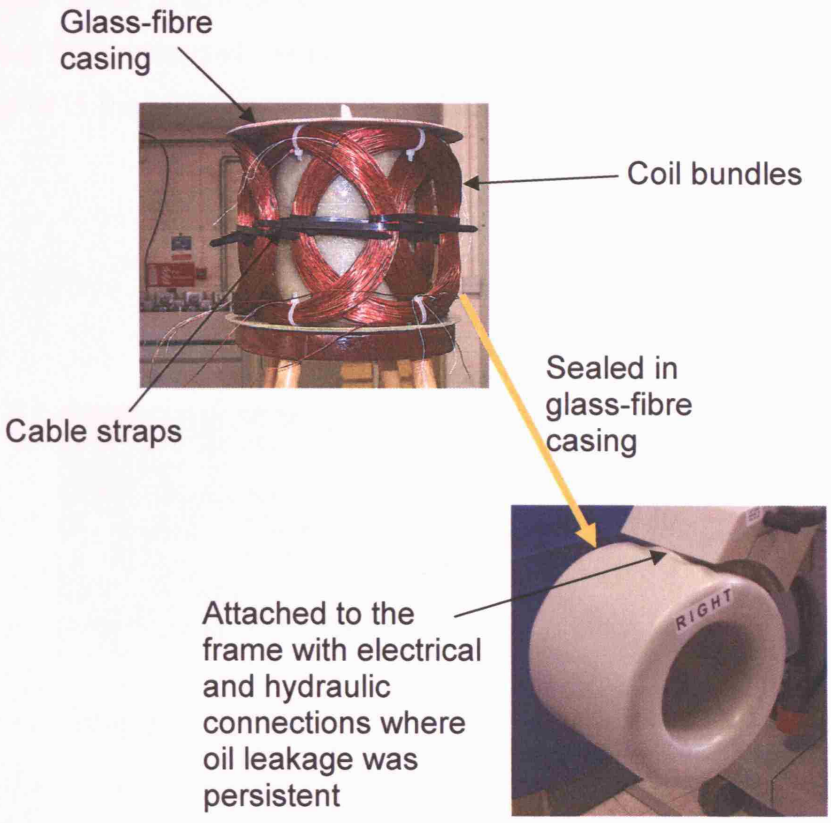


Figure 3.25 Electrical coil used in Mk 1 drive unit.

The performance of this coil was tested using an extending prosthesis which was mounted in series with a helical coil and a load cell. The prosthesis was then extended using the Mk 1 coil. The fixture and the load generated as the implant was extended are shown in Figure 3.26. The spring was calibrated to have a stiffness of 154.44 N/mm, which is a little less than the 170 N/mm as stipulated in Chapter 2 equating to the average force required for extension *in vivo*. The loadcell output was electrically very noisy due to the interference caused by the magnetic flux which was tested by turning the coil on and off. The result was that the rotor stopped spinning at about 730N load but restarted easily. It finally came to a complete halt at about 800N

load. Following extension under this load, the gearbox performance deteriorated rapidly and was not tested any further. Although at first sight the fluctuation in load might be regarded as an influence from the uncontrolled magnetic field, it could equally be due to the variation in flux density caused by poor coil construction creating fluctuating torque on the magnet. It was alleged that the measured load might be influenced by frictional stiction in the apparatus or in the sliding parts of the prosthesis.

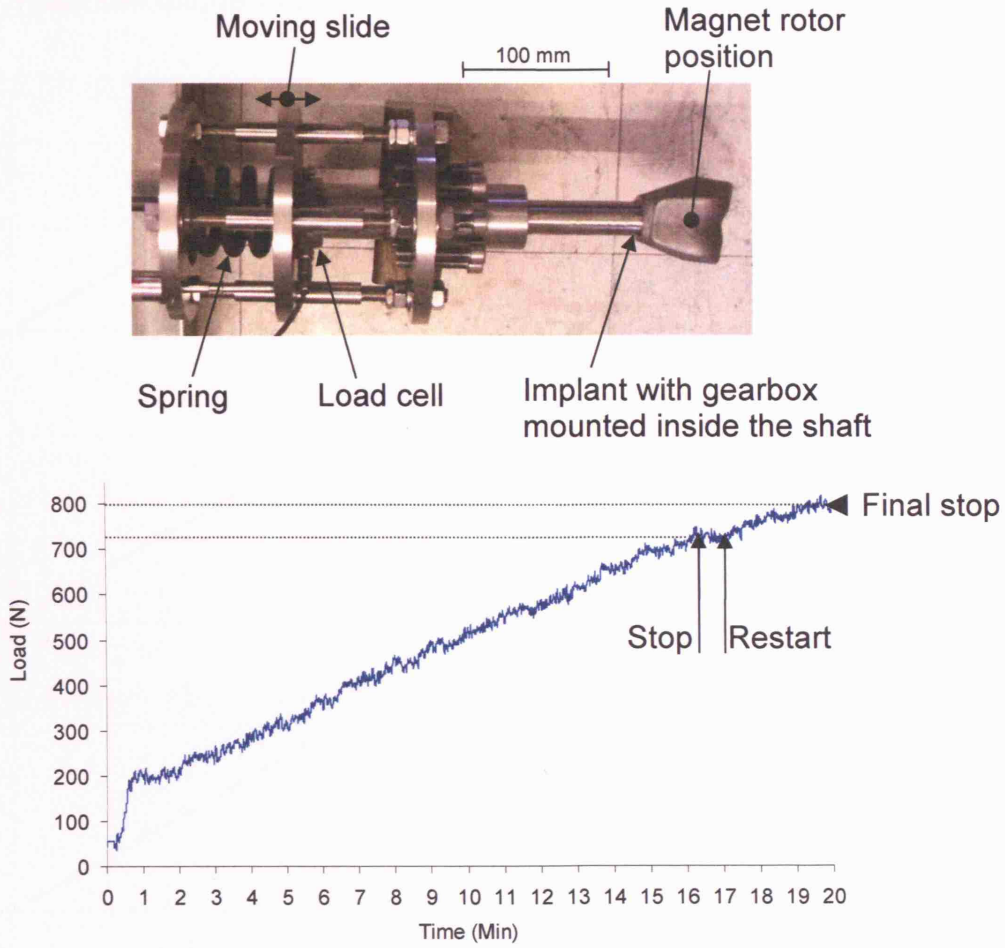


Figure 3.26 An implant complete with gearbox mounted in a fixture to measure distraction force. The graph shows load generated by old gearbox driven using Mk 1 coil.

When a new series of gearboxes became available the coil was tested again using a different method. In this set-up the gearbox was mounted in a shaft with the output from the gearbox directly connected to a torque transducer with an adjustable slip clutch to provide an incremental slip torque, as shown in Figure 3.27. The purpose of this direct torque measurement was to ensure that the performance of the coil was tested without interference from the testing apparatus. With the clutch adjusted for minimum torque transition, the motor was turned on and then the clutch was tightened every few seconds by a small amount. A series of incremental recordings were obtained until the magnet rotor stalled. It is clear from the graphs shown that the maximum torque at stall was barely 2.5Nm. The torque transducer was

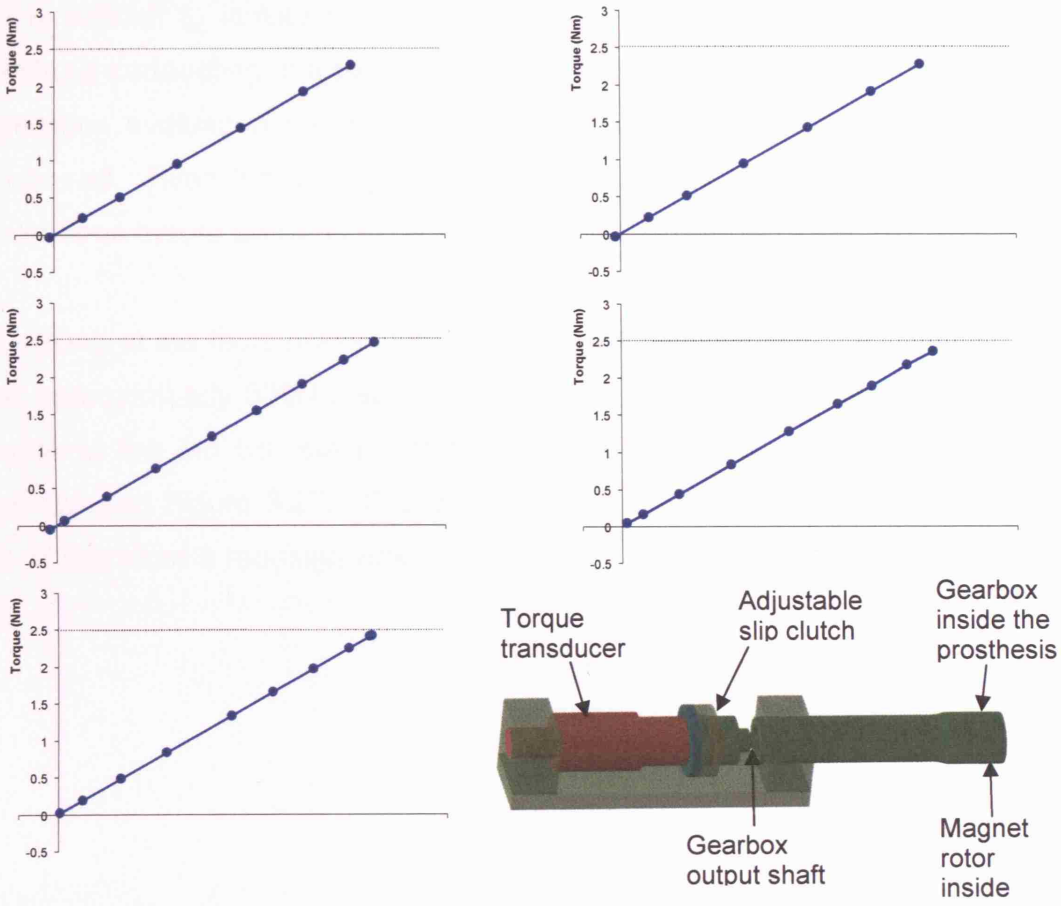


Figure 3.27 Torque measured using the 1st iteration modified gearbox with MK1 coil on five different occasions. Torque was direct measurement against a slip clutch where clutch pressure was incremented in steps.

calibrated and the calibration had a Pearson product moment correlation coefficient (R^2) of 0.9998.

From equation 3.10 it is clear that torque and load are directly proportional to each other for a given geometry and material combination. Hence for a 1300N load, a 4Nm torque was calculated and based on the same component geometry, I estimated that a 2.5Nm torque is produced by 812N load when used with a power screw. In fact this is almost the same load as the stall load shown in Figure 3.26 where the implant was extended against a spring. This correlation between the two experimental techniques provides reasonable confidence in the experimental set-ups and the calculations.

It is difficult to isolate the gearbox performance from the coil performance without conducting independent tests. However, it is clear from the original gearbox evaluation that the load safety factor was substantially lower than required. Even the strengthened gearbox took several design and material iterations before showing an acceptable level of performance.

Looking at the facts presented so far, the old gearbox with the old coil stalled at approximately 800N load, as shown in Figure 3.26. An improved gearbox against the old coil stalled at approximately the same load, as explained above and Figure 3.27. This clearly suggests that the coil was under rated and therefore a redesign was necessary.

3.4.2 New external drive concept

In a conventional electric motor, the stator and the rotor are constructed to channel magnetic flux across the gap where the gap is usually small for optimum coupling torque. As the gap increases, the coupling torque reduces and the efficiency decreases. To test the possibility of using the stator with lamination, an existing three phase AC motor (Figure 3.28) was dismantled by discarding the rotor. The stator windings were connected to a single phase programmable ACS-800 series inverter with sinusoidal filter, both donated by ABB Limited, Didsbury, Manchester, UK. With arbitrary parameters, the potential advantages of using a laminated stator operating on a single phase supply without cooling were established. A search was then conducted for commercially available motor laminates that would satisfy the size of aperture required for the patients. The main objective was to test the feasibility of using a laminated coil and to verify the result with a prototype device. Figure 3.29 shows a typical laminate and a completed Mk2 coil without casing. To minimise the overall length of the coil, the laminated stack was limited to 70mm so that the coil could be used close to the hip joint.

Figure 3.28 Carcass taken from a three phase motor to test initial feasibility of using laminated coil.

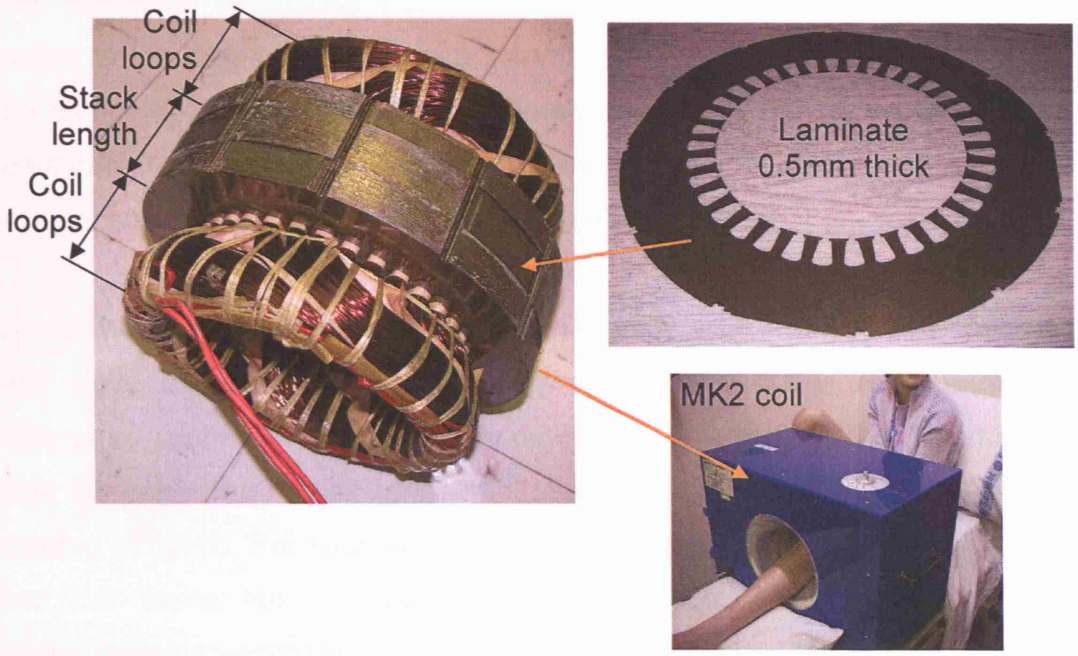


Figure 3.29 The laminates, coil construct and a completed Mk2 coil in clinical use.

A series ACS-800 inverter, mentioned above, was able to optimise the power and speed for a conventional 3 phase motor. In our application the speed was fixed at 3000 rpm to provide time dependent limb lengthening. The voltage was varied to provide the required flux density at the centre of the coil in order to produce a predefined torque on the magnet. In collaboration with Dr Steve Taylor in our Institution and using an Excel spreadsheet, calculations were performed to establish the following parameters:

- Copper wire diameter
- Number of turns per slot
- Coil voltage

To provide acceptable:

- Power consumption
- Efficiency
- Flux density at centre

The conductor resistance was maximised by connecting all conductors in series rather than parallel as in a conventional winding. This, together with the choice of an appropriate wire diameter and length, enabled the winding resistance to be matched with the inverter. A Mk2 coil shown in Figure 3.29 was constructed and enclosed in a Perspex box.

To examine the magnetic flux (induction) density profile, the space inside the Mk2 drive unit was scanned as shown in Figure 3.30, using axial and transverse probes in parallel paths along the long axis of the coil, starting from the centre of the coil with 10mm increments and with the magnetic field rotating at 50Hz. For simplicity it was assumed that the other half of the coil had the same flux density profile. RMS (root-mean-square) voltage measurements were taken using an induction coil calibrated in Tesla, using a Gauss meter positioned at the centre of the coil as a reference point. The Gauss meter also measures the flux density in RMS and not the amplitude. The scanned results are shown in Figure 3.31. Results show that there was no difference between the scans taken in a horizontal plane and those taken in a vertical plane. The results of the axial probe show very little flux within the lamination region (70mm in the mid section), whilst the vertically and horizontally positioned transverse probe show concentrated flux in this region. The volume outside the lamination had a diminishing flux for the transverse probe, but shows increased density for the axial probe. There was, however, a small difference between vertically and horizontally oriented transverse probe readings as the probe was moved radially outwards.

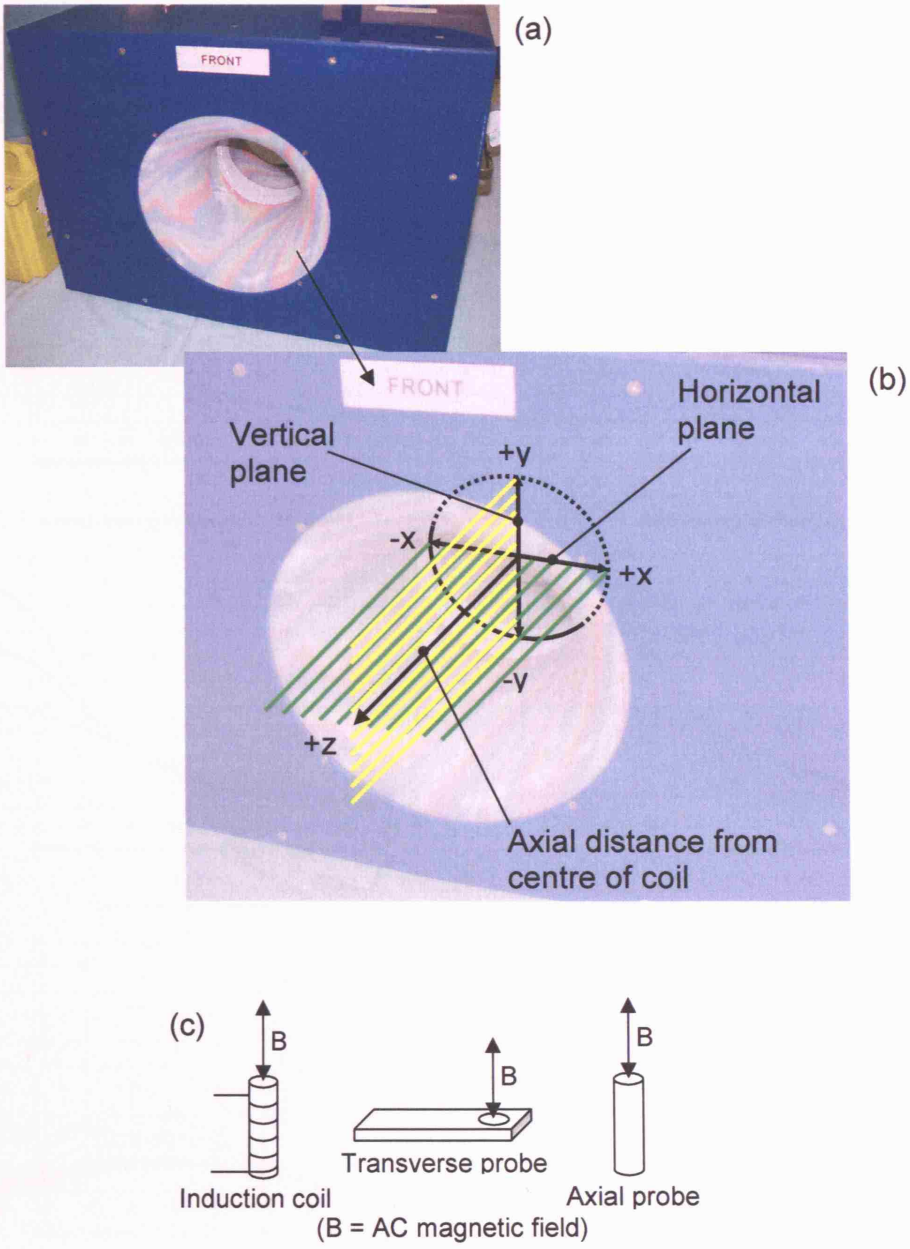


Figure 3.30 Flux density profile measurement conditions.
(a) Mk2 drive unit.
(b) Measurement patch along vertical and horizontal planes.
(c) Relationship between induction coil and Gauss probes used for the measurements.

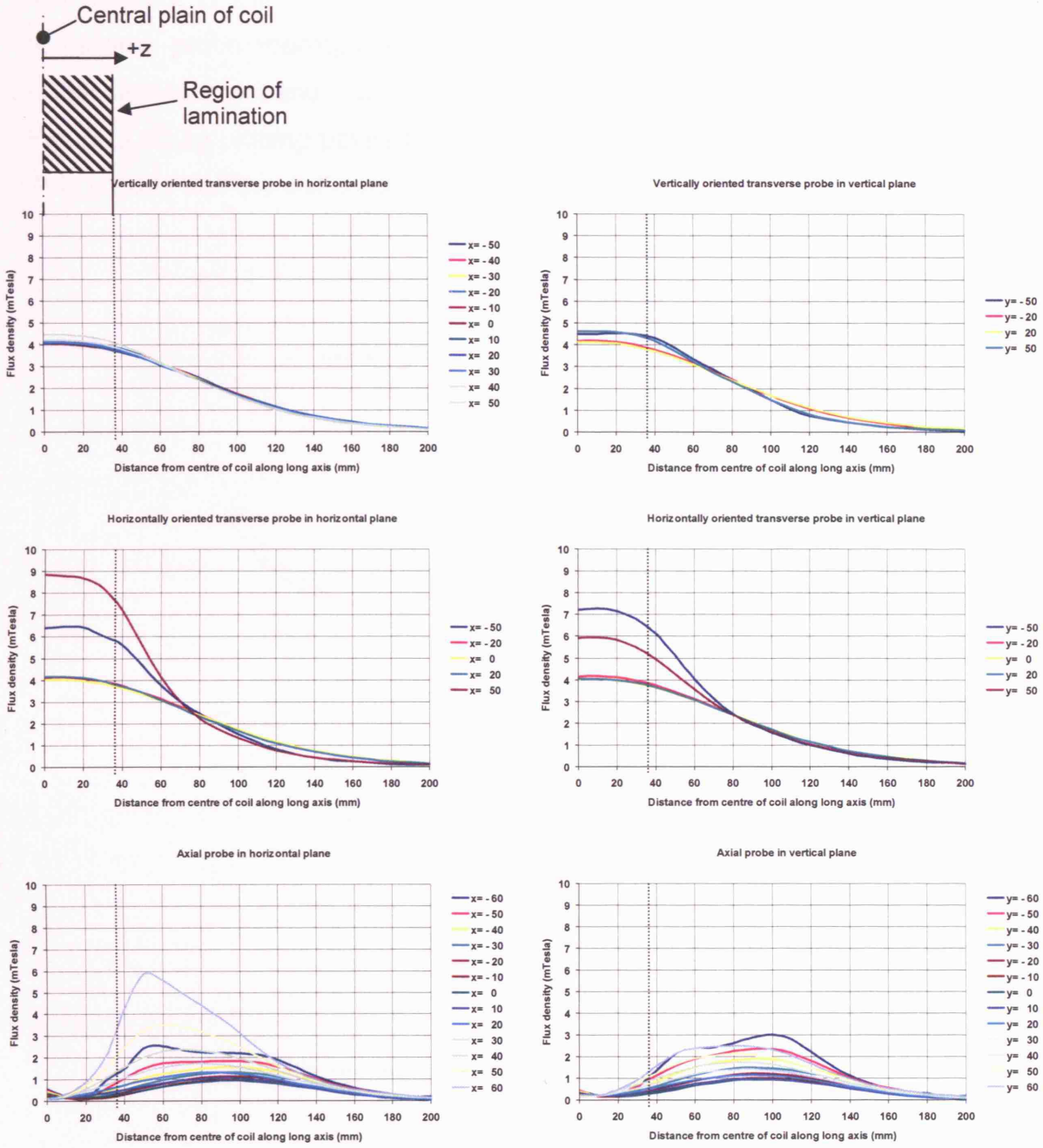


Figure 3.31 Flux density profile measured in RMS values inside the Mk2 drive unit measured along discreet paths in vertical and horizontal planes. Also shown, is the region of lamination.

A vertically orientated transverse probe showed little variation in readings with respect to the radial displacement. However, horizontally orientated transverse probe readings were the same for up to approximately 30mm radial displacement and increased from 30 to 60mm. This is demonstrated in Figure 3.32 by plotting points through an x-y plane at the centre of the coil. This implies that the coil construct is not symmetrical around the long axis.

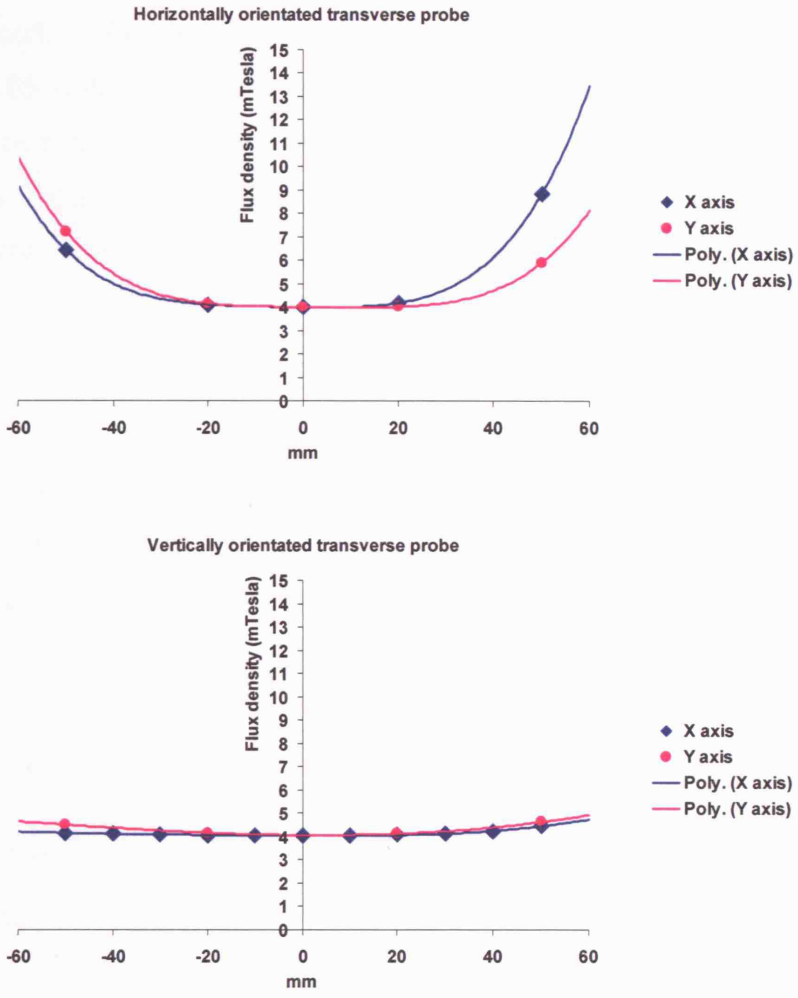


Figure 3.32 Flux density profile measured in RMS values inside Mk2 coil measured in x-y plane at the centre of coil along x and y axis. First graph shows probe with horizontal orientation and the second with vertical orientation.

The space within the lamination has a flux distribution which provides ideal conditions for magnetic coupling with a minimum flux density of 4 mTesla in the central 40-50mm cylindrical space. The flux density increases as the point is moved towards the inner wall of the coil. Axially beyond lamination, the radial flux gradually diminishes and the axial flux increases.

Also, as the magnetic coil energising voltage is increased, the flux density increases linearly ($R^2 = 0.9999$) over the expected range of operation. This is shown in Figure 3.33 where direct measurements were taken in the central part of the coil. All coils are currently standardised to operate at approximately 55 volts, but should an increased power be required for a new improved gearbox the device is capable of producing flux density well beyond that shown in Figure 3.33. Although not measured, the flux profile is expected to remain the same but increase proportionally with coil voltage.

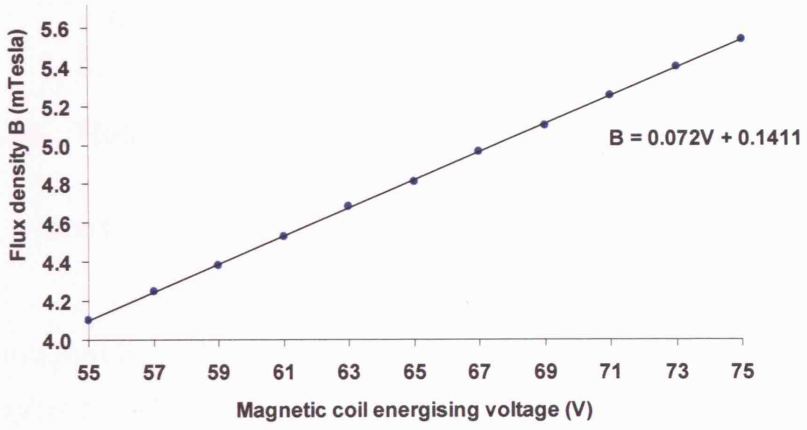


Figure 3.33 The effect of increasing the energising voltage on the flux density in the centre of the magnetic coil.

3.4.3 External drive / magnet coupling

A test was carried out to determine the stall torque within the laminated region. To do this I used a pulley system with a weight which produced a known torque on the magnet, as shown in Figure 3.34. The pulley was constructed from medical grade 316L stainless steel with a fine machined surface and a surgical suture (W199 4 MERSILK braded silk 6 metric) was used as a string. Torque generated by the bearings was minimised by using low friction bearings and for this simple test it was assumed negligible. At constant speed, the inertia of the magnet, the pulley (10mm diameter) and the shaft (4mm diameter) plays no part in the torque and hence for a steady state condition these were assumed negligible.

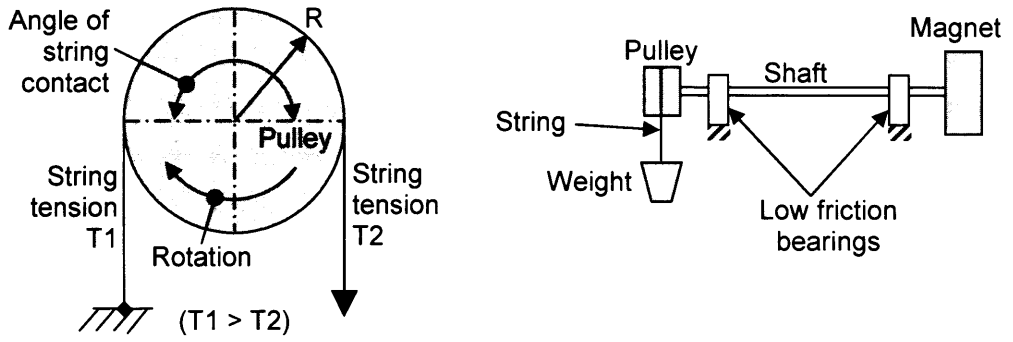


Figure 3.34 Rotor stall torque measurement using pulley with tension string.

With the magnet fixed, the coefficient of friction was experimentally assessed using weights on either side of the pulley imbalanced by an exact amount to create a slow and consistent sliding between the pulley and the string. The coefficient of friction was calculated from the following Firbank equation, taken from Mechanical Engineering Design, First Metric Edition (1986), Pages 624-625, which assumes no centrifugal forces and uniform friction along full contact.

$$T1 / T2 = e^{(\mu\theta)} \qquad \textbf{Equation 3.12}$$

Where, T1 and T2 are tensions on both sides of the string

μ = Coefficient of friction

θ = Angle of string contact = π

The coefficient of friction was calculated as 0.12761 at confidence interval of 0.00197 at 99.9% significance level (n=8). The magnet was then placed at the centre of the coil and a set of five stall torques were recorded. The magnet was then moved to the right (+x) and measurements repeated. The minimum, maximum and average for each position was calculated as shown in Figure 3.35. There was a noticeable increase as the rotor was moved off centre, which appears to be linear as shown by the regression analysis performed on actual measured points from all four sites. Since the rotor diameter (shown in dotted circles) is relatively large, it was assumed that the non-linearity seen in the magnetic flux density does not influence coupling.

The minimum torque generated at stall was just over 2mNm. Having made all material and design adjustments to the gearbox design as described in section 3.3 to provide a torque carrying capacity of 4Nm and assuming all design objectives are practically achieved in the construction of a gearbox, it can safely be assumed that the torque amplification provided by this gearbox is in the region of 2000 times.

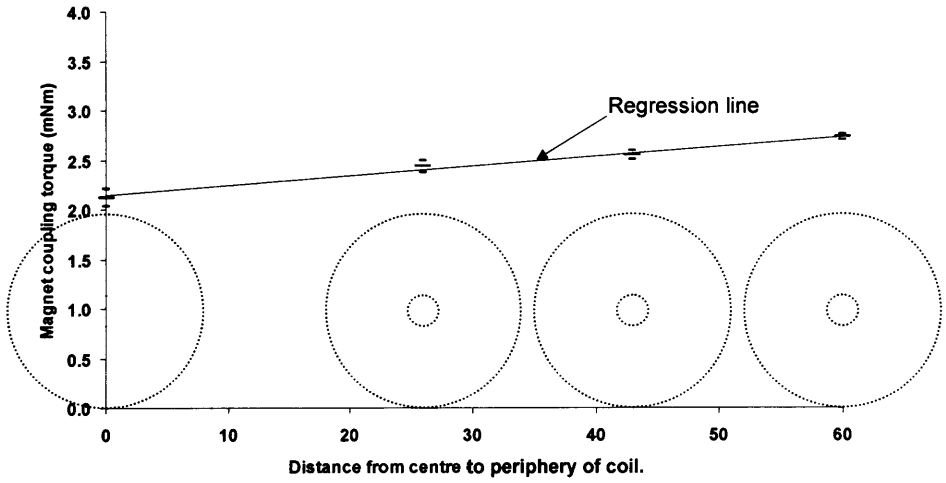


Figure 3.35 Rotor stall torque at four positions: at centre, 26mm, 43mm and 60mm to the right of the coil centre. Also shown is the size of the magnet with dotted lines.

3.5 Overall performance and final refinements

At various stages of the development, the gearbox, the screw with a telescoping shaft and the coil coupling as a complete unit were tested for performance by mounting the gearbox together with a magnet in a real implant shaft. The shaft was mounted in a fixture shown in Figure 3.26, where the inner telescoping shaft was extended against a loadcell and a compressive spring. In Chapter 2, the minimum performance requirements were defined as 600N start-up load and 170 N/mm rate of increase thereafter, to a maximum of 1300N. This is shown by the dotted line in Figure 3.36. This is what I set out to achieve and it was taken as a baseline for comparison for all future work.

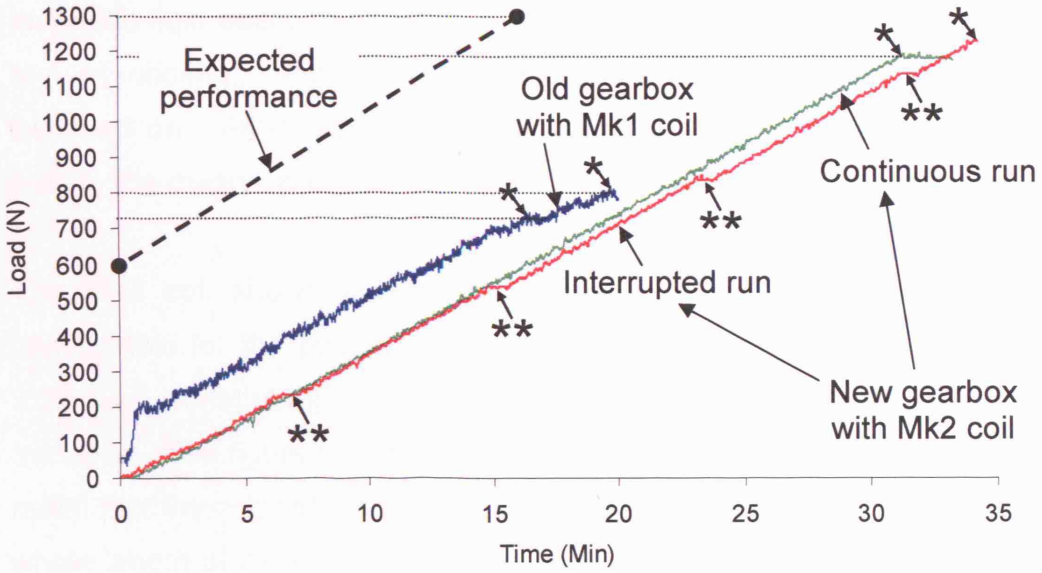


Figure 3.36 The graph shows expected performance represented by dashed line. It also shows the performance of old gearbox with old coil and the performance of new gearbox with new coil with continuous and interrupted runs.

* Stall loads
** Intended stop and restart

The graph also shows the load carrying capacity of the original (old) gearbox coupled with the Mk1 coil previously discussed in section 3.3. As stipulated before, this did not provide enough scope to lift a starting load of 600N and it barely managed to lift 800N load before stalling. This is well short of a peak load of 1300N that it is expected to carry.

The new gearbox with Mk2 coil has produced a much more acceptable performance. It has operated non-stop up to 1200N load before stall. This is a little short of 1300N peak load, but is close enough to provide confidence in construction. The new gearbox with Mk2 coil has proved capable of restarting with any preload and continued to extend thereafter without hesitation. This is demonstrated by the stepped line.

Therefore in general, the new Mk2 coil has successfully achieved the design objectives which included a compact laminated structure with concentrated magnetic flux, easily transportable and a single phase drive unit that did not require cooling. Importantly it produces no sound or vibrations when switched on. Although there was a question regarding the imbalance flux profile, the magnetic coupling produced is superior to the Mk1 coil.

The Mk2 coil shown in Figure 3.29 was still too large and it was not comfortable for the patient. The next generation Mk3 coil shown in Figure 3.37 was constructed. This is much easier to manipulate and easy to transport. The figure also shows flux density profile obtained by scanning the radial flux intensity at the centreline and at 60mm cylindrical path along the whole length of the coil. This shows a steady uniform flux at the centre of the coil and six-lobed profile nearer the inner wall of the coil. This explains the non-uniformity found in the horizontal and vertical planer scans obtained in the Mk2 coil (see Figure 3.31 and 3.32). The coil is constructed from lamination which has 36 slots with 6 slots per phase for each of the three phase supplies. As one would expect, the boundary between adjacent phase conductors has an effect of reduced flux intensity whilst within each phase bundle the flux intensity is higher. This evaluation compliments the previously

obtained flux density measurements and at the same time addresses the question raised for the non-uniformity in the initial measurements.

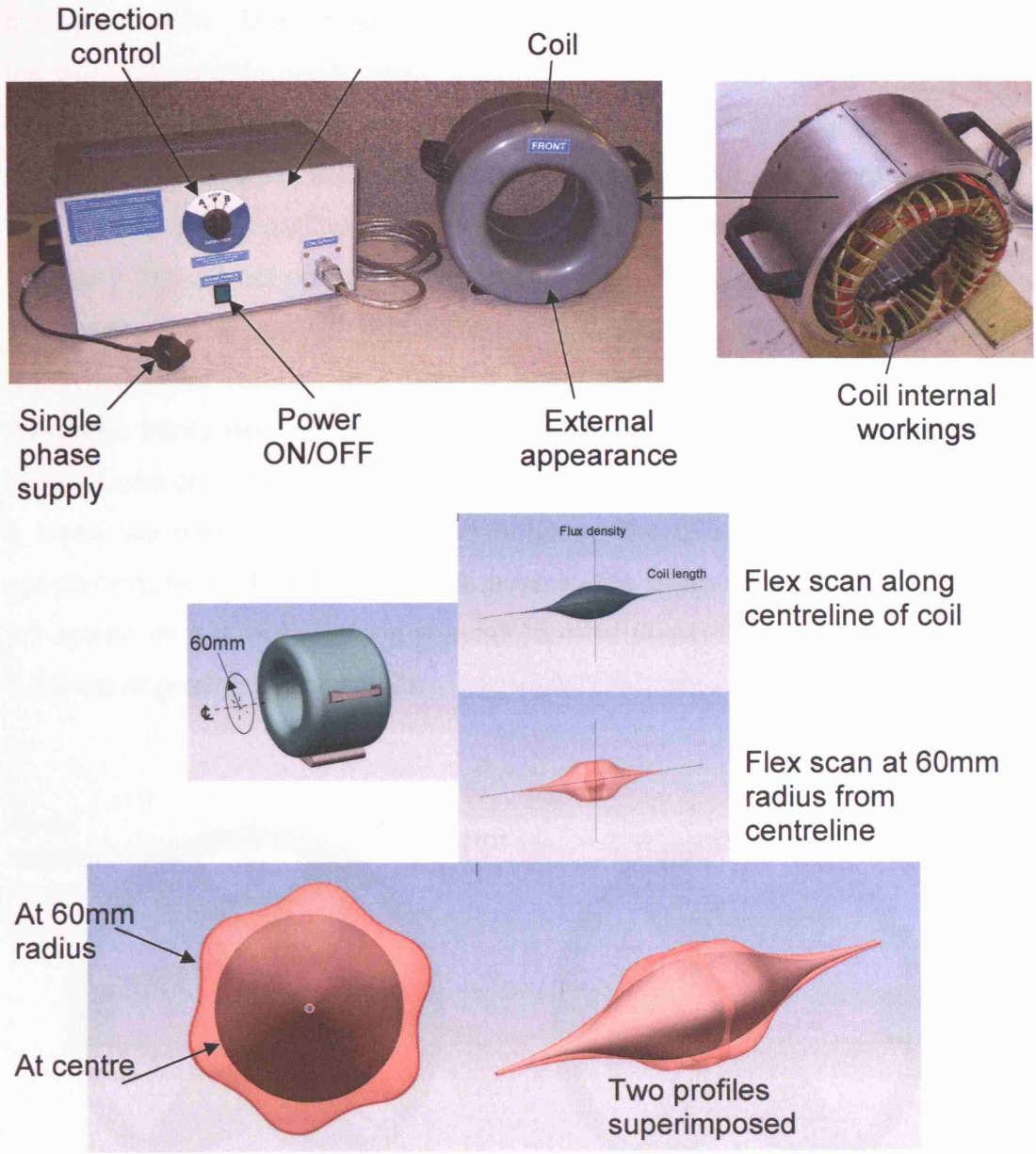
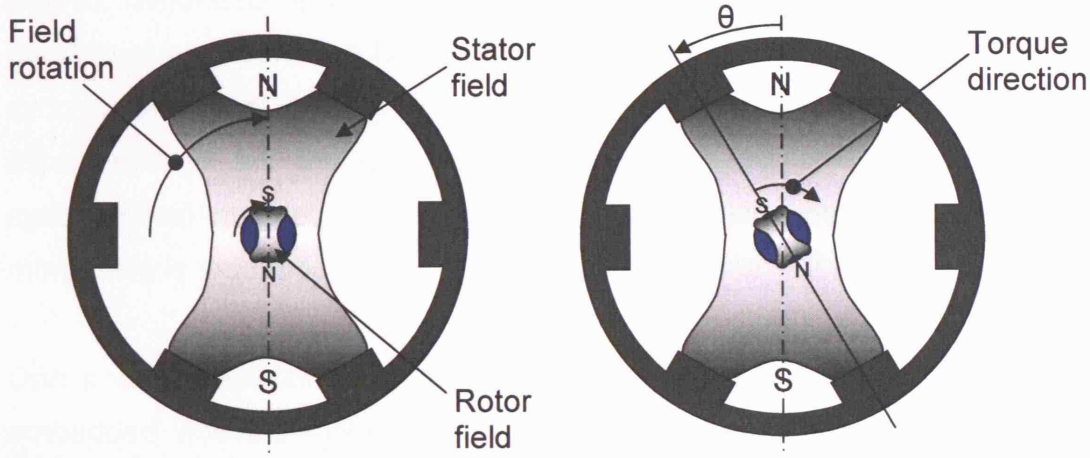


Figure 3.37 Top left hand pictures show Mk3 drive unit with a compact coil and a control box for ease of transport and use. Top right hand picture shows inner construction of the coil. The graphical pictures below show the radial flux intensity profile at the centreline and at 60mm radius along the length of the coil.

3.6 Sensing and feedback

An implant containing a stationary magnet is first placed inside the coil and then the coil is switched on. As the magnetic field is generated and starts to rotate, it captures the implant magnet and forces it to rotate in synchronisation. Due to inertia of the magnet and other rotating elements of the gearbox, a gradual increase in speed is required before reaching the full speed of 3000 rpm. At the start, the speed is increased linearly over a period of 2 seconds which is sufficient to pull the magnet into a synchronised spin. In a steady state condition, both magnetic fields interact with each other in harmony by attracting opposite poles. As the torque on the magnet increases, the alignment retards by a few degrees and it is this shift in relative angular rotation that dictates how much torque is generated by the magnetic interaction. This is shown diagrammatically in Figure 3.38. The magnet can only lag by a few degrees under the influence of a torque before it loses the harmonised interaction between the two fields and falls out of synchronisation. Therefore, in this system the magnet is either spinning at full speed or it is not. During a synchronised state, the rate of extension is 0.25mm of growth every minute.



a) No torque generated

b) Torque generated is proportional to angle θ

Figure 3.38 A snapshot of magnetic field interaction and the relationship with torque.

The coil itself produces no sound when switched on and there is no indication of anything happening with the external drive unit. When running, the gearbox produces a whirling sound with a spectrum of frequencies emanating from different parts of the gearbox. It is quite possible to hear the gearbox producing an audible sound, sometimes loud enough to hear a meter away from the patient. When the magnet has failed to synchronise or has fallen out of synchronisation, the noise turns to a pulsed frequency which sounds like humming caused by the oscillating magnet as the rotating field passes at 50Hz. Since, in a synchronised state the rate of prosthesis growth is fixed, timing the period of extension indicates the amount of growth provided that the magnet is synchronised. In a noisy environment or when the gearbox has very little vibration, a stethoscope is needed to hear the sound. Sound from the prosthesis travels along the bone and is picked up at the other end of the bone, such as the greater trochanter, knee condyles or at the ankle. As most stethoscopes contain magnetic metal parts which are susceptible to magnetic vibration, for a stethoscope to work properly, it is important that it is placed on a part of the limb that is 20cm or so away from the magnetic coil.

Due to manufacturing tolerances, no two gearboxes sound the same and a great deal of experience is necessary in identifying the sound to judge the synchronisation status. The existing protocol relies on an operator with experience to tell the difference between a synchronised and a non-synchronised magnet. To reduce the operator element, more controlled monitoring is required.

One possible solution is to use wireless telemetry in combination with an embedded encoder inside the prosthesis, to obtain information from the implant such as the number of turns that the magnet has produced. An encoder mounted at the back of the magnet could sense the magnet rotation, which can be used to determine the amount of extension the prosthesis has produced during a session. With some additional memory electronics, a cumulative extension count may be established making it self monitoring.

The feedback could then be linked with the power controls for the coil to switch on and off as required. This type of monitoring system has not been tried and probably the strong magnetic field generated by the coil will swamp the signals generated by the telemetry unless the telemetry transmission is placed outside the coil space. However, this may not be a practical proposition. Furthermore, the encoder which is usually made of a hall-effect transducer, probably needs to differentiate the weak signal generated by the magnet within a strong magnetic field produced by the coil itself. There is another complication of power supply for the implanted electronics which needs to be made available on demand.

One of the main disadvantages with electronics inside the prosthesis is that it makes manufacturing very complicated. Also, any additional component inside the prosthesis requires space, which limits the available growth of the implant.

To overcome all of these problems, an external Intelligent Growth Monitoring (IGM) System is proposed for future development, providing a closed system that can be very effective. As I have proved successfully that a stethoscope is a very useful tool to pick up sounds from a part of the bone that is away from the coil and that there are distinct differences in the sound depending on whether the magnet is spinning or not, this acoustic method could be used to control the growth in the prosthesis.

Such a system is shown in Figure 3.39. A strategically placed microphone captures the vibrations from the patient and a spectrum analyser determines the rotor status. The patient is supplied with a smart card which provides patient records and a past history of lengthening procedures. Based on the card information and clinical input to the amount of extension required, the system then determines the direction and duration of the magnetic coil. Once authorised to continue, it constantly monitors the progress and reports any problems it encounters and records cumulative time, and hence the growth of the prosthesis as it progresses. The current control system used for the coil is software driven and it is possible to link it to this monitoring

system to automatically adjust the magnetic field strength within a predefined bandwidth, thus optimising the gearbox and other related performances. With such a closed loop automated system, there is always a need for a panic button should the patient feel any discomfort and requires the system to stop. All this information, including any complication, is recorded on the smart card for the next lengthening session. If properly set-up, this system removes the requirement of an experienced operator and may even be used to monitor remotely, allowing the patient to take the equipment home or for an Institution to obtain help remotely from experts should complications occur.

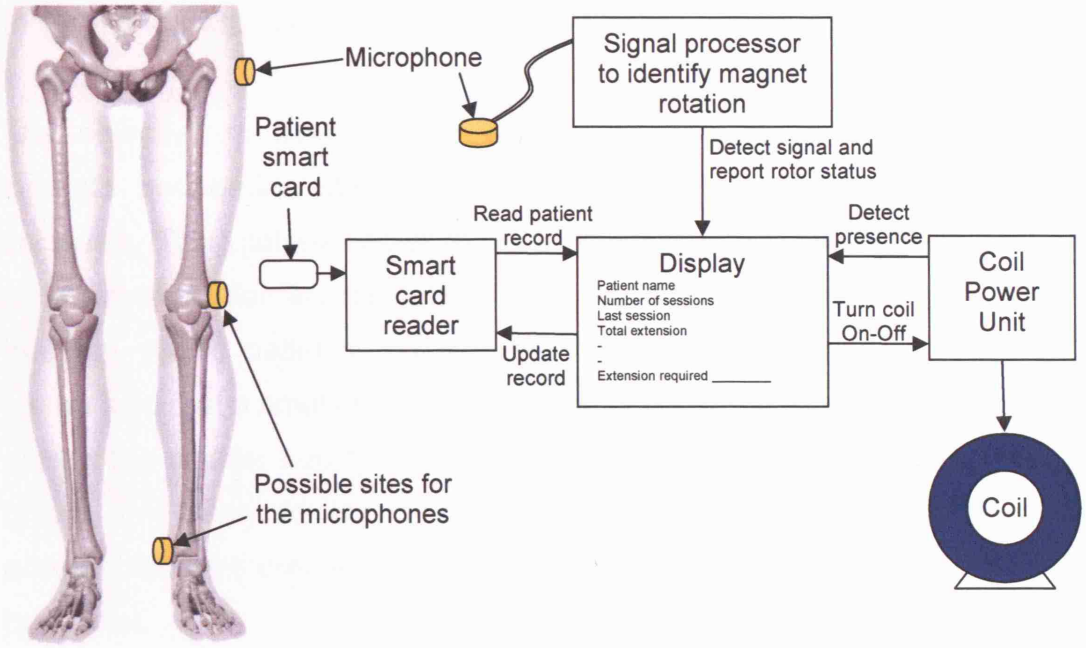


Figure 3.39 Main elements of the external Intelligent Growth Monitoring (IGM) System.

3.7 Design justification against alternatives

Looking back on the design development phase, exactly what has really been achieved? To answer this, let us look at each item separately.

The implant:

Prosthetic construction in terms of intended application is associated with patient requirements and therefore there is not much more that can be addressed. However, it has been suggested in the analysis that we have a modular attachment for the telescoping section integral with the drive components to allow replacement of the growth element without disturbing the fixation. It would be highly desirable to have a growth element with attachment mechanisms at both ends and make it available in modules of 30 to 100mm growth in multiples of 10mm.

The objective to evaluate the telescoping section to ensure adequate strength and define strength characteristics for smaller sizes has been achieved. The analysis shows that a 14mm spigot is strong enough, giving a minimum shaft diameter of 22mm. However, this is not small enough to cater for very young patients. There are two options: increase the material strength so that a smaller diameter can be constructed or have two sizes and expect the smaller size to have a higher failure rate because as the patient grows it is likely to fail. Ethically speaking the second option is not acceptable and therefore investing in a stronger material would be extremely beneficial.

Are there any alternatives for the telescoping section? The first thought is that the shaft needs extruding and without telescoping it cannot get longer. So, in terms of a prosthetic construct as a metallic object, the answer is almost definitely no. Then what about utilising a bone transportation technique in combination with an implant? In theory this is possible, using a mechanism that moves the prosthesis away from the bone creating bone extrusion. This, in my opinion, warrants further investigation. The concept

behind this technique is that the stem, together with the plateau of the prosthesis, is gradually retracted away from the bone interface allowing bone ossification to take place within the gap. The trick in the concept is to allow the prosthesis to carry the load and at the same time retract to form new bone under external control. Here we are looking at implant migration in the opposite direction to the applied load and a biological response creating new bone, both happening at the same time.

The Ilizarov technique described earlier where, following an osteotomy of the bone, two halves are held together with a small gap in between them by an external mechanical frame with pins, has demonstrated the viability of the technique quite well by forming bone mineralization in the gap. Hyodo *et al.* (1996) used an interlocking intramedullary rod for fixation and a traction cable to move the fragments apart in the canine femur. This demonstrates an alternative technique without using transfixing pins. Similarly, Mitsugi *et al.* (2005) transported alveolar bone in the curve direction of the dental arch using a distracter in combination with an orthodontic arch wire for transport guidance in 22 patients with good result. The only difference between these and the proposed technique is that the rate of bone regeneration in our application needs to be very slow to match the growth rate of the patient. This is likely to cause bone unification as the mineralization rate would probably exceed the required growth rate. So, in addition to bone transportation, we need either to control the rate of calcification, have a mechanism preventing bone unification or have a means of breaking the bond on demand.

Internal drive mechanism:

The objective to evaluate original implant design for performance and establish a baseline for further development has been achieved. The baseline peak force required for the telescoping section as defined in Chapter 2 was 1300N. To lift this load, a torque of 4Nm was needed to turn a 7mm screw. The original gearbox was only able to generate enough power to lift 800N tested using new external drive unit. The original implant

assembly was not tested and had assembly issues such as lubrication and seals. The original gearbox (Ø18mm x 19mm long) was taken and developed further to provide the required torque.

Based on the above findings the gearbox was redesigned giving tested performance as listed below.

- Lift a maximum peak load of 1200N.
- Restart with any preload up to 1200N.
- Provide smooth and consistent performance (in conjunction with the new improved external drive unit).
- Easy assembly allowing controlled lubrication of the gearbox parts.

This was achieved at the expense of a bigger size gearbox with the final size being Ø21.5mm x 25mm long. This is clearly a disadvantage and further work is necessary to reduce the size of the gearbox, bringing it in line with the original gearbox. To achieve this, either the load capacity needs reducing, which may not be the best option, or better materials which are hard and have higher strength are required. This area needs further investigation.

There is also a shortfall in load capacity this is not very much but may have a noticeable failure rate as the product becomes widely used and is exposed to higher loads. This also emphasises the need for a more powerful gearbox.

As space is an issue for the growth of the patient, can the complex drive mechanism be placed outside the prosthesis? If the current diameter is too large, then this may not be possible. If this were possible, the device may be used selectively where the space is available. This warrants a clinical review.

What are the alternatives? A hydraulic system may be employed as described by Hildebrandt (US patent US3976060), but the complications are much compounded. The fluid not only needs to expand the prosthesis, but it

is also required to carry the load applied by daily activities unless a ratchet or other non reversing mechanical mechanism is employed. Pressure generated to lift 1300N can be as high as 16MPa for a 10mm piston and then to feed at this pressure would require a very powerful miniature pump. The fluid reservoir also requires a balanced approach so that a pressure differential is not created as the fluid is drawn. At this point the strength of the construct may become a critical issue as this volume of fluid needs space to be stored, unless somehow a filter is used to draw the fluid straight from the blood supply. This would have to be doused with antibacterial compound for safe use. For safety reasons this may not be the route to take.

External drive unit:

This too was assessed and the old drive had several inherited complications as described previously. The main objective to improve efficiency and make it portable, along with consistent operation, was achieved. Although the device is heavy, it is easy and safe to use practically anywhere. There are, however, some improvements required to control the device, as described in the previous section, to make it self monitoring.

The result presented in this chapter satisfies the project aim listed in paragraph 1.6, (A), (b), first three bullet points [Chapter 1, page 48].

3.8 Future recommendations

Although a vast amount of effort has gone into developing this device, there is more that can be done to improve the technology. In the previous section the following has been recommended for future development.

(a) Develop a growth element with attachment mechanisms at both ends and make it available in modules for 30 to 100mm growth in multiples of 10mm.

(b) Investigate stronger material for the growth element to reduce the overall size.

(c) Investigate bone extrusion using a bone transportation technique in association with an implant.

(d) Investigate reduction in gearbox size by utilising stronger material. Yield strength well in excess of 1000 MPa is needed.

(e) Investigate remote placement of the gearbox to maximise growth potential.

(f) Develop closed loop control for the drive unit utilising a vibration monitor and software control.

CHAPTER 4

TESTING

4.1 Introduction

In the development of orthopaedic implants, stringent controls are now in place worldwide to minimise the risks in using these implants for the treatment of patients. The European Council directive 93/42/EEC concerning medical devices and Food and Drug Administration (FDA) in the United States regulates the introduction of implantable medical devices in those respective countries. Both of these regulatory controls are generally respected by most countries in the world. As a result of that, a number of countries have adapted at least one of these regulatory controls with some additional requirements specific to their own needs. There is a trend for unified world regulations, but this has a long way to go.

The growing prosthesis we have developed has two major parts. The implant that is constructed to replace a part of the patient's bone and is for long term invasive use. This is classified as Class 2b under the Medical Device Directive. As the implant is also constructed for the treatment of an individual against a prescription, it is further classified as a Custom-Made device. The drive unit which extends the prosthesis after insertion is, on the other hand, classified as Class 2b. It provides power for the prosthesis to make it grow, but since it is not customised and is used for more than one patient, it is CE approved in order to be placed on the market.

A Class 2b implantable device can be validated in one of two ways. The product may be type tested in which case there is substantial knowledge of similar devices on the market and additional changes are marginal. Therefore market review is all that is needed to justify the use of the new device. If the device has a significant change and there is no other similar device on the market, then the device must be tested and if required a clinical trial undertaken to evaluate the risks. Since this growing prosthesis is intended for patients requiring customised implants there is no scope to conduct a clinical trial, but this does not preclude thorough testing before using the concept in order to minimise the risks. As there is no clinical trial for custom implants and even though the concept may already be tested and

validated, the Directive requires maintenance of stringent patient records for the lifetime of the device. The implantable devices are usually 'Single Use' only. The drive unit which is used for multiple patients is a part of the implant concept and requires testing, validating and CE approval prior to use.

The non-invasive extending prosthesis inclusive of the drive-unit, has a number of new features and therefore these features require justification for use. The following considerations were given:

- The section that contains the telescoping mechanism, inclusive of the screw, has been in use for over ten years in the minimally invasive growing prosthesis with very few complications. It therefore requires no further validation or testing. To support this, a clinical review was conducted and is reported in this Chapter.

- The gearbox is accommodated in a cavity that is sealed using O-ring seals and this was identified as a testable feature. A test was done and is reported in this Chapter.

- The gearbox is a complex device and it was identified as part of the initial objectives to fully performance validate. The performance of the gearbox as it was developed is reported in Chapter 3.

- The external drive unit has a unique construction and it too was identified as part of the initial objectives to fully performance validate. The performance of the drive unit as it was developed is reported in Chapter 3, along with the development of the gearbox.

- To define the performance of the whole mechanism, a simulated test was conducted to test the functionality of the system. A test was done and is reported in this Chapter.

- The external drive unit was also validated to meet the requirements of the Directive demonstrating compliance to BSEN 60601 – Medical Electrical Equipment. A theoretical analysis of the Electromagnetic Field (EMF) was conducted and is reported in this Chapter.

- The implant contains a permanent magnet and it is generally intended for patients receiving treatment against bone or soft tissue cancers. These patients require regular examinations to monitor the progression of the disease, often using Magnetic Resonance Imaging (MRI) and/or Computer Topography (CT) and/or routine radiographs. It is well understood that magnetic material must not be present in the MRI unit as it is liable to damage the equipment or may cause injury. Experimental scans were taken to establish the effects caused by the magnet on the imaging processes and the observations are reported in this Chapter.

The objectives therefore are:

- Report on the clinical review of the telescoping section used in the minimally invasive growing prosthesis and how that fits in with this device.
- Outline and conclude *in vitro* test conducted on O-ring seals.
- Outline and conclude *in vitro* simulated test conducted on the whole mechanism to test the overall functionality of the system.
- Test prosthesis safety for routine radiological and MRI examinations.
- Conclude the findings of all these tests.

4.2 Clinical overview of telescoping shaft

The aim of this section is to review the minimally invasive prosthesis in order to understand how the telescoping mechanism has survived in practice. To do this, the existing records at the Department of Biomedical Engineering, Stanmore of patients with a minimally invasive growing prosthesis were analysed for mechanical complications. These are patients for whom minimally invasive implants were constructed at this Institution and were inserted at various hospitals throughout the world.

Between April 1992 and February 2006 there were 354 patients requiring primary treatment for bone cancers and 35 patients requiring revision implants for previously inserted collar type growing prostheses. These patients were treated with minimally invasive growing prostheses. Of these patients, 51 had a second, 9 patients had a third and 1 patient had a fourth revision minimally invasive growing prosthesis for various reasons. One further patient had an adult type prosthesis to replace a minimally invasive growing prosthesis and 5 patients had their prostheses retrofitted with collars for mechanical complications. There were a total of 451 minimally invasive growing prostheses and 67 (14.9%) of them required revision implants.

Of those 67 revised implants, 31 (46.3%) had mechanical complications as shown in Table 4.1. The most significant problem was collapsing or jamming of the drive mechanism shown in Figure 4.1. In this design the gear wheel is integral with the screw and it slowly turns when the worm is rotated using a key. Ten full turns of the worm causes one full rotation of the screw, which pushes the telescoping shaft out by 1mm. When teeth on the gearwheel or on the worm become damaged, rotation of these parts becomes very difficult and in some cases they ceased to operate. The other phenomenon noted was that with the drive mechanism fully operational (i.e., no apparent damage), it was capable of rotating the screw either forward or more commonly in reverse, causing the implant to change length without external intervention. The exact process is not fully understood, but it is thought to be

the result of the longitudinal micro motion between the telescoping parts that allows the screw and worm to rotate relative to each other.

Primary cases	354
Revision from collar type grower	35
First time total	389
Revised to 2nd minimally invasive grower	51
Revised to 3rd minimally invasive grower	9
Retrofitted with collars	5
Revised to 4th minimally invasive grower	1
Revised to non-grower	1
Total revised	67
Mechanical problems	26
Infected	12
Loose	10
Fully extended	9
Other	7
Fractured Bone	2
Dislocated hip	1
Total revised	67
Mechanical problem and revised	26
Mechanical problem and not revised	5
Total mechanical complications	31
Collapsed 10 Revised with another implant 5 Not revised 5 Treated with collars	20
Jammed	4
Fractured telescoping shaft	3
Fractured tibial stem	2
Fractured grower screw	1
Worm migrated	1
Total mechanical complications	31

Table 4.1 Analysis of the minimally invasive growing prostheses.

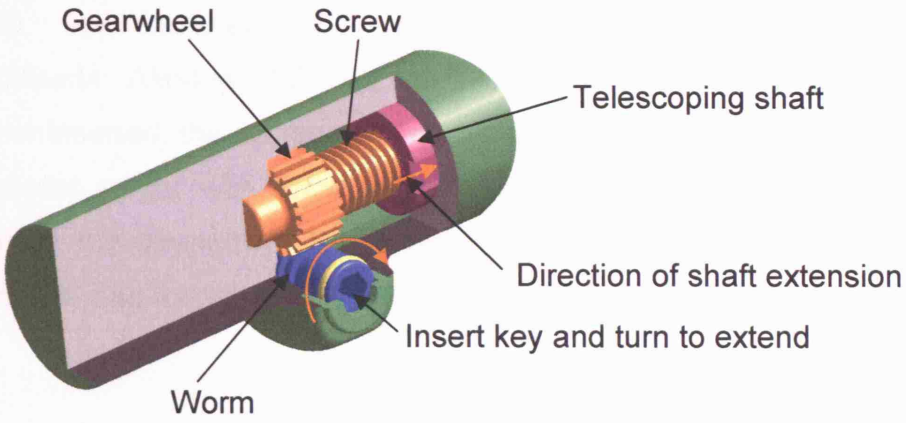


Figure 4.1 Minimally invasive growing prosthesis showing working components.

Looking at the telescoping section inclusive of the screw, there have been four complications: three fractured telescoping spigots and one fractured screw. The fractured screw was a result of over lengthening by 2cm which led to the screw supporting full body load causing fracture. This was a surgical planning error where the implant was over extended beyond the recommended safe maximum for the stability of the telescoping parts. On the other hand, three fractured spigots had 13mm spigot diameter with 8mm screw giving 2.5mm wall thickness. In addition, one of the spigots had diametrically opposing 1mm deep flats, thus locally reducing wall thickness to 1.5mm. Due to this reduction in wall thickness, it was no great surprise that this shaft had fractured. This was a spiral fracture indicative of a torsional failure. This design with flats is no longer in use. All spigots are manufactured with longitudinal key slots to allow telescoping, whilst preventing rotation between sections. One spigot had fractured just where the key slot terminates, acting as a stress raiser. This patient was reported

to be a keen football player. The other shaft was reported as fractured, but this was not evident on the x-rays taken at the time.

From this analysis, the conclusion is that the flats across the spigot reduce strength and are not recommended. The fractured screw was the result of an over extension. Two fractured spigots were 13mm in diameter with 8mm inside screw threads. Although, this is a very small failure rate in comparison with the number inserted, the design used in this non-invasive prosthesis has a 16mm diameter spigot with 7mm screw giving 4.5mm wall thickness, greatly improving the strength. Over extension is possible with the non-invasive prosthesis and therefore adequate instructions to the clinicians must be provided.

4.3 Gearbox output shaft seals

The gearbox is mounted inside a titanium shaft and the output shaft from the gearbox is passed through a seal housing to allow direct drive with the screw that pushes the two telescoping shafts apart (Figure 4.2). The purpose of the seal housing is to allow the shaft to rotate but prevent body fluid entering the gearbox cavity and similarly, prevent liquid paraffin lubricant escaping into the shaft section.

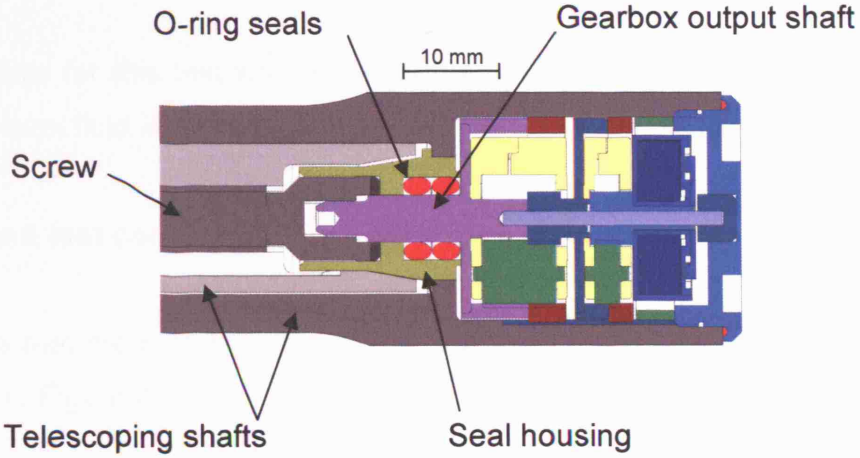


Figure 4.2 Seal housing with O-ring seals.

O-ring seals were produced from implantable medical grade silicon (MED 4750, supplied by NuSiL Silicone Technology, Carpinteria, CA, USA). In an ideal situation the O-ring seals would be made from slightly more rigid polymeric rubber than MED 4750, but these materials are not implantable and other implantable grade polymers do not have adequate elasticity to act as a compressive seal.

With a rotating shaft, as it turns, the fluid from either side tends to lubricate the interface between the shaft and the O-ring and as a result, some fluid passes beyond the seal. The amount of ingress is governed by pressure created by the seal. The idea of having a second O-ring is to double the protection, minimising the ingress.

This type of seal is not truly hermetic and a polymeric seal is liable to create balanced pressure either side of the seal by vapour and gas permeation. Therefore any differential pressures caused by temperature variation or any other mechanism will permeate gasses or, in this case, water vapour to equalise the pressure. The permeation can not be controlled and it is expected that once the implant is inserted and the body temperature is reached, the pressures will balance and stabilise.

Objective:

The objective for this test was to perform a leak test at the seal interface in terms of visual fluid ingress.

Method and test conditions:

In order to test the effectiveness of the seal a simplified set-up was created as shown in Figure 4.3.

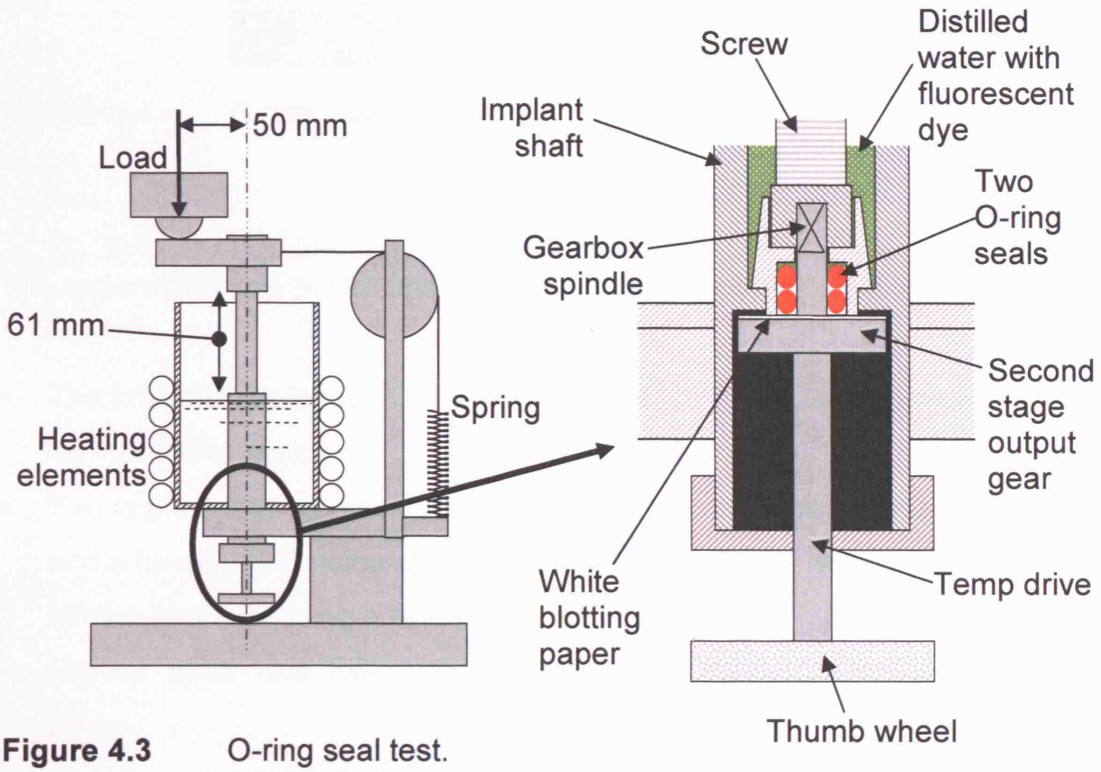


Figure 4.3 O-ring seal test.

Instead of using a complete gearbox, only the output shaft with an integral ring gear was used with an extension piece and a thumb wheel to turn the shaft by hand. The other end of the shaft was attached to the screw to allow telescoping of the prosthesis in a normal way. The shaft of the prosthesis and the telescoping cavity were filled with distilled water doused with fluorescent yellow dye. In between the ring gear and the seal housing, a sheet of white blotting paper was placed to absorb any fluid seepage. It was anticipated that if clear water was used and it penetrated the seals, there would be no trace of leakage, particularly if the leakage was small and the water evaporated rapidly. Hence blotting paper was used to collect any of the fluid that leaked through the O-rings, leaving a sample of fluorescent dye on the paper. The actual apparatus is shown in Figure 4.4.

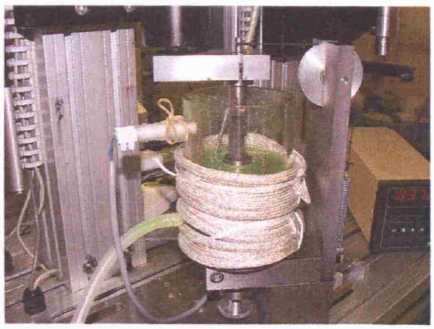


Figure 4.4 O-ring seal test set-up.

The experiment was set up and the test conditions were as follows:

- The implant was loaded between 0 and 750N at 1 Hz using square waves for 1.6 million cycles.
- The implant was loaded with 50mm offset to create bending in the screw and a counter balancing spring was used to introduce lateral tilt during the offload phase causing a wobble.
- Grower shaft was fully extended to create maximum bending on the screw.
- Fluid was maintained at body temperature throughout test duration.

- The loading cycle was stopped and the screw was turned by hand approximately every 0.5 million cycles to create 5mm of extension. It was then turned back down to start position before restarting the cyclic loading.
- Fluid level was checked once a day and if required was topped-up with fresh distilled water.
- The blotting paper was examined at the end of the experiment after removing the assembly and allowing it to dry in oven for 24 hours.

Conclusion:

A fully extended prosthesis cyclically loaded at a body weight in a simulated body environment showed no signs of leakage onto the blotting paper positioned on the other side of the seal, after 1.6 million cycles. The upper seal on the fluid side (shown in Figure 4.5) had a significant amount of metal wear debris, indicating normal wear and motion above this level. It is possible that the fluid might have seeped under the first O-ring but it was not possible to detect using this method. The dismantling process used would not allow preservation of the interface. The examination of the blotting paper showed no evidence of dye penetration by discolouration and therefore the level of seal was considered satisfactory under these conditions.

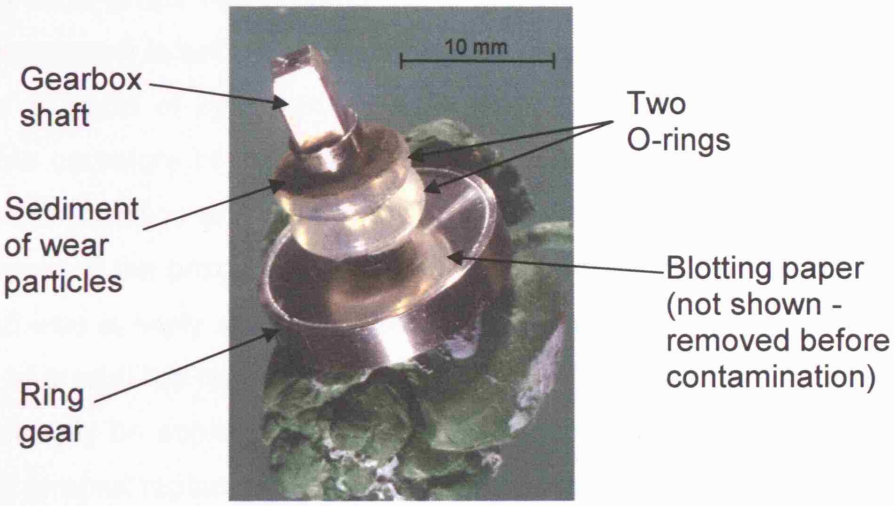


Figure 4.5 The O-rings with wear debris.

4.4 Fatigue test

A complex device such as this growing prosthesis with remote drive input is best tested as a whole system to ensure it is working to specifications and that there are no adverse complications. The implant consists of a telescoping shaft extended by a magnet connected through a gearbox, which is usually inside titanium and/or cobalt chromium molybdenum alloy prosthesis. The magnet is driven by an externally rotating magnetic field at a fixed speed of 3000 rpm.

The most heavily loaded bone with bending and torsion is the femur. The load applied on the femoral head is transmitted through the diaphysis down to the knee joint. Load line in the tibia is almost coincidental with the diaphysial axis, whilst in the femur it is inclined as shown in Figure 4.6. The load on the femoral head is increased by the action of abductor and iliotibial tract forces, which results in a medial bending of the proximal part of the femur. Further down the femur the iliotibial tract has the effect of reducing medial bending as described by Birnbaum *et al.* (2004). Also, with the cork screw shape of the femur, load applied at the head results in a small torsional moment in the diaphysis. ISO 7206, Part 4 "Implants for surgery – Partial and total hip joint prostheses – Determination of endurance properties of stemmed femoral components", specifies a test method for determining the endurance properties of stemmed femoral components and describes how the specimen is set up for testing. The test is applicable to prostheses that have a plane of symmetry or have preformed anteversion of the neck or double curvature of the stem. A replacement of a proximal femur loses the abductor function and as a result, it experiences noticeably reduced loading. However, if the proximal femoral bone is maintained, as in a distal femur, the prosthesis is likely to experience more complex loading conditions similar to that of a total hip replacement. Although this standard for testing hips could not directly be applied to the growing prosthesis, it is similar to the test for a distal femoral replacement where the resection is high. For this reason it was decided to use the ISO 7206 protocol and test a distal femoral prosthesis.

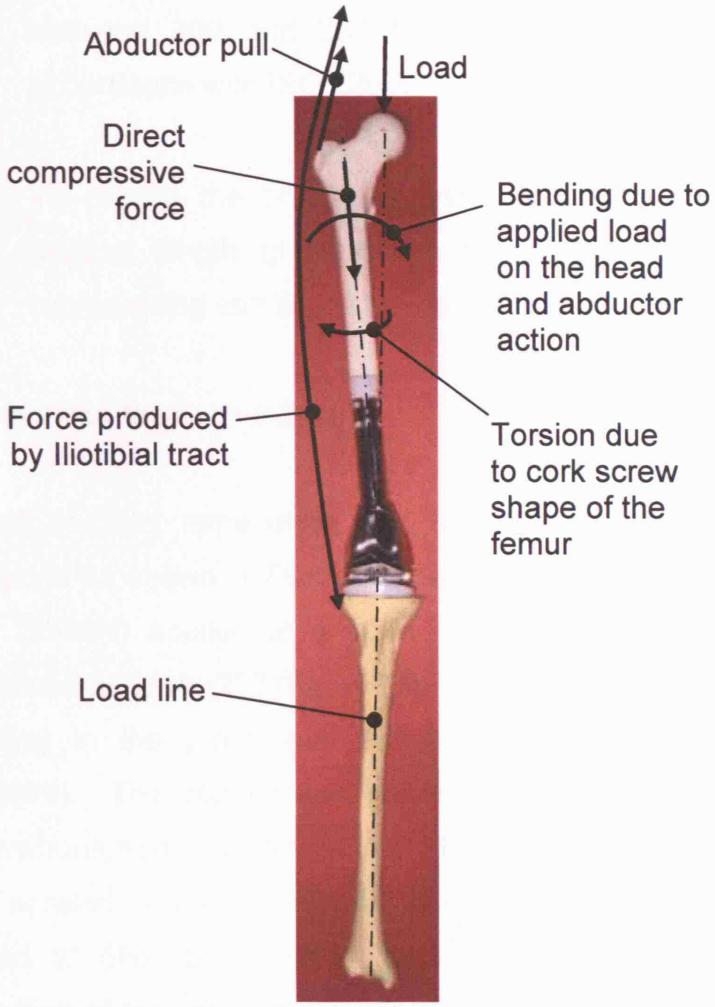


Figure 4.6 Loading condition in the lower limb.

In vivo distraction force measurements outlined in Chapter 2 indicated that if the distraction was limited to 4mm, the average load was 343N with only 2 out of 76 measurements exceeding 800N. Therefore, it was considered appropriate to apply a static load of 800N to represent soft tissue tension in this experiment.

Objective:

The objective was:

- To test two distal femoral replacements set at maximum extension, immersed in Ringer's solution at body temperature with cyclic loading

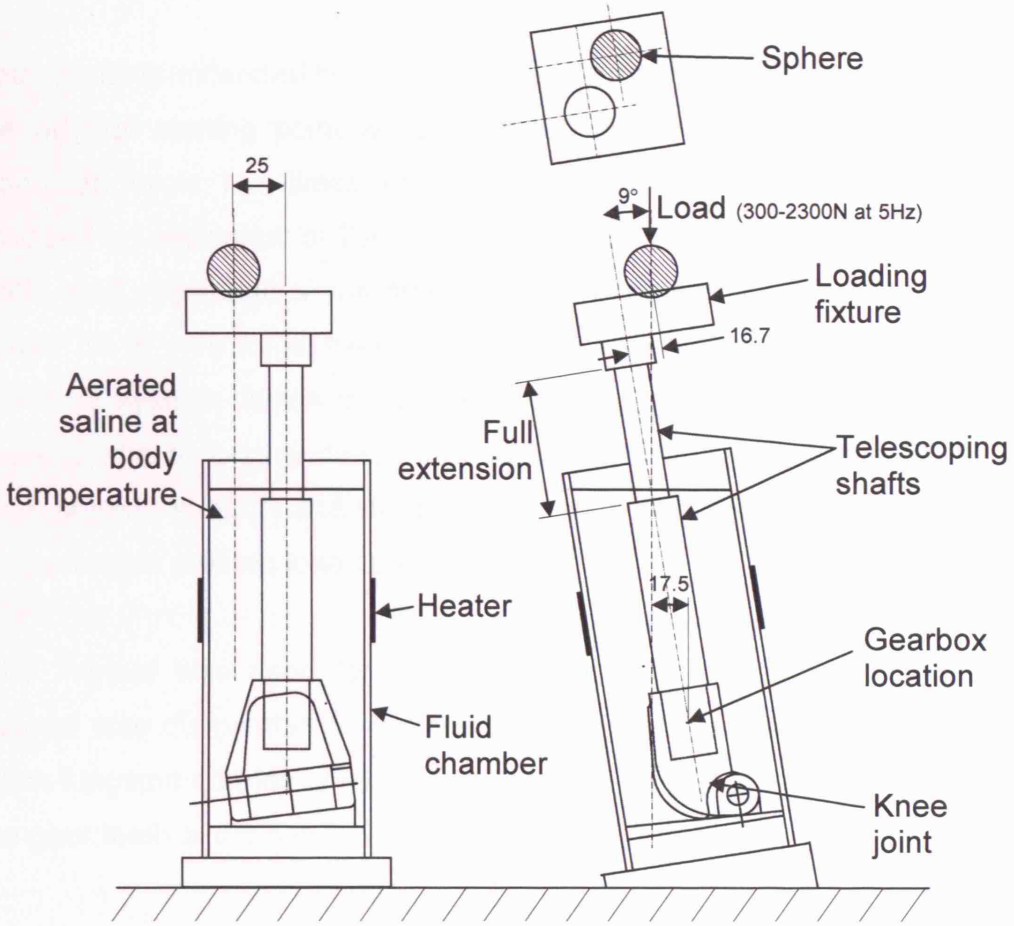
between 300 and 2300N at 5Hz for 5 million cycles applied in accordance with ISO 7206.

- To extend the prosthesis using induction coupling and reverse to original length at least five times against a constant 800N load, representing soft tissue tension.

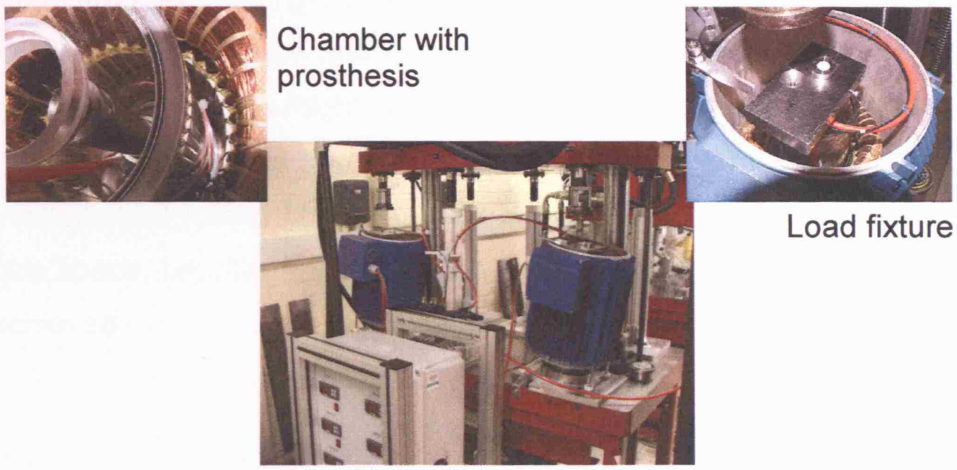
Method and test conditions:

Based on past experience and the ISO standard, a test protocol was produced as shown in Figure 4.7 for a distal femoral replacement. A single load (2300N) applied at a point proximal to the implant produces direct compressive load (2271N), medial bending (56.8Nm), a torsional moment (9.0Nm) in the prosthesis and a hyper-extension moment at the knee (40.3Nm). The implant was immersed in Ringer's solution (as defined at www.whonamedit.com/synd.cfm/2119.html) maintained at body temperature and aerated using a peristaltic pump. At first the implant was cyclically loaded at 5Hz, but it soon became apparent that because of a large deflection of the test components the hydraulic system was not able to apply the required peak load. As a result, the frequency was reduced to 4Hz, which was able to produce a sinusoidal wave form between 300 and 2300N load. During the test period both implants were extended by 7mm against a static load of 800N and then retracted by the same amount of extension using a magnetic coil, once a day during weekdays and left running continuously at weekends. The experiment was allowed to complete 4 million cycles, during which time it was extended ten times. Due to the time allocated for the experiment, it was not possible to continue beyond 4 million cycles. This was as a result of running the experiment at 4Hz instead of 5Hz, which was planned originally.

The external drive units were set to provide a 4 mTesla flux density at the centre of the units using inductive coil as described in Chapter 3.



a) Schematics of the prosthesis and applied loads.



b) Experiment set-up with coil.

Figure 4.7 Protocol and experimental setup for full fatigue test.

Conclusions:

Both implants extended by 7mm under a static load of 800N and retracted to the original starting point without hesitation and were able to repeat this extension cycle ten times over 4 million fatigue cycles. This process provided an equivalent of 70mm extension plus 70mm of retraction with 800N static load. Although at the time of this experiment 800N load was chosen based on *in vivo* force measurements and the limitations imposed by the hydraulic system, which could only provide a static load for the extension process, the recommendation now is to test the growth against a variable load, starting at 600N and stopping at much higher load of 1200N to provide a much more realistic load condition.

One implant was used for other trials and for demonstration, whilst the second was dismantled for examination. Apart from visual thinning of the black tungsten carbide coating, there was no other sign of damage to any of the gear teeth in the set.

The drive coupling performed well without hesitation. In this experiment the flux density in both drive units was set to 4 mTesla and the magnets were manufactured from a single batch. Any deviation from these parameters will affect the coupling torque and if increased, it will produce an increased load carrying capacity which might damage the gearbox. One possible solution is to make the coupling as strong as possible within permissible levels of EMF and introduce a torque limiting device in the gearbox. However, this would require space, resulting in a reduction in the maximum extension that could be achieved.

4.5 Electrical safety and CE approval of external drive unit

All medical electrical equipment must comply with National and International Standards to ensure safe and proper use of the device. With the external drive unit there are two requirements that need careful assessment. Being an electromagnetic device, the EMF generated by the device must be within the safe exposure levels for both the patient and the operator. Also the device must be constructed and labelled to minimise risks by improper use. BS EN 60601-1, Parts 1 and 2 listed below control the construction and validation and because the validation process needs to be independent for CE marking, this task was conducted by SGS Yarsley Limited, a Notified Body employed by the Competent Authority in the UK. The labelling and part of the construction was changed to meet the requirements before being certified.

- BS EN 60601-1-1:2001 "Medical electrical equipment – General requirements for safety – Collateral standard – Safety requirements for medical electrical systems"
- BS EN 60601-1-2:2002 (IEC 60601-1-2:2002) "Medical electrical equipment – General requirements for safety – Collateral standard – Electromagnetic compatibility – Requirements and tests"

Level of EMF in the coil:

One of the main functional properties of this device is that it generates a magnetic field and this must be adequately controlled to minimise exposure. To understand the level of exposure and how it fits into the regulatory requirements, it is important to evaluate the EMF characteristics of this device.

Measured flux density within the coil inner volume was less than 10 mTesla RMS, as discussed in Chapter 3, section 3.4.2 and shown in Figure 3.31. The flux density value against the inner wall of the coil, where the patient is required to rest the limb, was measured less than 15 mTesla RMS as

indicated in Figure 3.32. Furthermore, the flux density in the central part of the coil was measured with the energising voltage ranging from normal voltage of 55V to the expected maximum 75V for the current induction coupling, as shown in Figure 3.33. Although, the power capacity of the coil is significantly higher than this, to protect the gearbox, the power was limited to 75V. Since flux density is proportional to the energising voltage, the peak EMF exposed to the patient is below 25 mTesla RMS at 50Hz.

The guidelines outlined later in this Chapter categorise the magnetic field as static or dynamic. The degree of static field and the rate of change in flux density have a threshold beyond which they are considered harmful to living tissues. Figure 4.8 shows the theoretical sinusoidal flux density (B) and the corresponding flux gradient (dB/dt) for 25 mTesla RMS at 50Hz. The analysis shows that the maximum peak flux gradient is 11.107 Tesla/sec.

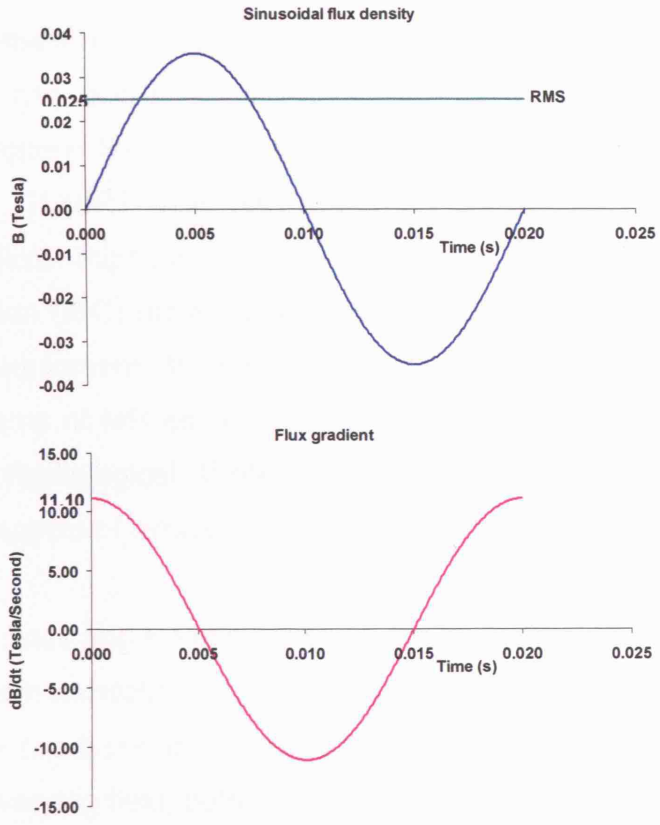


Figure 4.8 Sinusoidal flux density (B) and the gradient (dB/dt) in the coil at 75V, 50 Hz producing peak flux density of 0.025 Tesla RMS.

The guidelines:

Electromagnetic field presents a number of patient and operator related safety issues. The main factors that need considering are:

- Intensity of the static field
- Length of exposure to the static field
- Gradient of time-varying field
- Length of exposure to the time-varying field
- Part or whole body exposure
- Body temperature rise due to the exposure
- Peripheral nerve and muscle stimulation
- Biological effects
- Acoustic noise

The International Commission on Non-Ionising Radiation Protection (ICNIRP) has published guidance on general exposure to time-varying electromagnetic fields. This guidance is for occupational and general public exposure. ICNIRP have also published guidance for Magnetic Resonance (MR) clinical exposure to patients. The International Electrotechnical Commission (IEC) provides a standard (IEC 60601-2-33) for manufacturers of MR equipment to follow. This standard focuses on the safety requirements of MR equipment used for medical diagnosis. In the UK, the National Radiological Protection Board (NRPB) publishes guidance on several aspects of exposure to magnetic fields.

The Medicines and Healthcare products Regulatory Agency (MHRA) outlines these recommendations for Magnetic Resonance Equipment in Clinical Use. There are two types of magnetic fields that we have to consider: static field and time varying field, both requiring different levels of controls.

Static field:

The examples of NRPB and IEC levels for whole body exposure to static magnetic fields are shown in Table 4.2. These levels are all above 2 Tesla. In our application the external drive unit does not produce a static field and therefore it was concluded that this requirement does not apply.

NRPB 1991		IEC 2002	
Level	**Field (Tesla)**	**Level**	**Field (Tesla)**
Uncontrolled	<2.5	Normal operating mode	<2
Upper	2.5 - 4	First level controlled operating mode	2 - 4
-	-	Second level controlled operating mode	>4

Table 4.2 NRPB and IEC exposure levels in a static magnetic field. The level signifies the degree of controls required during exposure. (Taken from MHRA – Guideline for Magnetic Resonance Equipment in Clinical Use)

Time-varying field:

The NRPB patient and volunteer exposure limits to time-varying magnetic fields are shown in Table 4.3. Here, the time period 't' is the duration for one complete cycle or, in the case of a sinusoidal frequency, duration of half a cycle. The "Uncontrolled Level" signifies exposure level below which there are no controls required and it is considered safe. The "Upper Level" signifies exposure limits at which it is advised not to exceed without ethical committee approval. The range in between is recommended with caution and continual monitoring of the subject.

Similar values were published by FDA in their guideline indicating the levels of dB/dt that are below the level of concern, i.e. are safe to use. These values are:

For $t > 120\ \mu s$	$dB/dt < 20$ Tesla/sec
For $120\ \mu s > t > 12\ \mu s$	$dB/dt < 2400/t$ Tesla/sec
For $12\ \mu s > t$	$dB/dt < 200$ Tesla/sec

In our application the time t is 10ms and the gradient is less than 11.2 Tesla/sec which is considered safe by both of these standards.

Duration of field change	**Uncontrolled level dB/dt (Tesla/second)**	**Upper level dB/dt (Tesla/second)**
t < 2.5μs	950* (1 W kg^{-1})	1300* (2 W kg^{-1})
2.5μs < t < 45μs	2.4 x 10-3/t	1300* (2 W kg^{-1})
45μs < t < 120μs	2.4 x 10-3/t	60 x 10-3/t
120μs < t < 3ms	20	60 x 10-3/t
t > 3ms	20	20

Table 4.3 NRPB exposure levels in a dynamic magnetic field. [Where, 't' is time period, 'Uncontrolled level' signifies exposures below which it is considered safe and 'Upper level' signifies exposure limits which it would be inadvisable to exceed without ethics committee approval. The range in between the two requires caution and measured control.] (Taken from MHRA – Guideline for Magnetic Resonance Equipment in Clinical Use)

Peripheral nerve stimulation (PNS):

J P Reilly (1989) published mean peripheral nerve stimulation threshold dB/dT(Tesla/sec) versus ramp time (the curve known as the 'Reilly curve') and he showed that for ramp time greater than 0.4 msec, the PNS threshold was just over 60 Tesla/sec whilst for very short durations, less than 0.2 msec, the threshold could be much higher. By doing this Reilly linked the exposure level with time. It is recommended by the MDA that the equipment should be calibrated for PNS threshold using volunteers and then reduced to 80%.

In our application the ramp is well below 60 Tesla/sec and therefore nerve stimulation is not possible.

Conclusion:

In our coil the magnetic field rotates at 50Hz and since it has a sinusoidal form, the time period is 10ms with a flux gradient (dB/dt) of 11.107 Tesla/sec. The guideline limits the maximum time varying exposure level to 20 Tesla/sec for it to be safe requiring no added controls. Looking at it in another way, since 20 Tesla/sec is considered absolutely safe, there is scope to increase the magnetic field by 80%, but this needs careful assessment since there are metallic parts in the prosthesis that can induce localized EMF causing discomfort to the patient. From this analysis it is concluded that our device in its current form is safe to use. However, it is recommended that if the device power is increased beyond 75V, we need to measure the flux gradient to ensure there are no variations in the vicinity of a metallic implant and that the eddy currents within the implant are not causing any adverse effects.

4.6 Safety in routine examination

In the modern medical industry with the latest technological advances, there is a large amount of equipment in use for diagnosis and treatment using magnetism and/or radiation of some sort. It is hypothesised that there might be some kind of interaction between medical equipment and the magnet in a prosthesis. There are guidelines for implants such as the heart pacemaker where patient safety is of paramount importance since the patient's life depends on the pacemaker and therefore the restrictions are very stringent. However, there is nothing at present to suggest safety levels for an implant containing a permanent magnet.

There are basically three types of imaging techniques used on a routine basis for cancer patients. These are Magnetic Resonance Imaging (MRI), Computer Topography (CT) and conventional radiographs. It is important to look at these individually.

Magnetic Resonance Imaging (MRI):

It is common knowledge that no magnetic material be taken, to the area where the MRI is housed. No matter how small the magnetic object, it will have a force exerted upon it by the strong static magnet that is inside the equipment. One to two Tesla scanning equipment are commonly used and there are five and even ten Tesla equipment in existence. Force generated depends on the object size, the magnetic properties of the object/scanner and the distance between them. Coupled with this, when the secondary pulsed frequency is activated during a scanning sequence the forces increase considerably.

As scanning equipment is very expensive and sensitive to foreign electromagnetic influence, which was thought by most to affect the calibration of the equipment, no one was willing to test the effect of the magnet on a scanner. After a long countrywide search Dr. Barrie Condon, a Consultant Physicist at the Institute of Neurological Sciences in Glasgow, accepted a

magnet for testing. He used a 1.5 Tesla Siemens Magnetom set with SE 2000/15msec scans with 300mm field view and 10mm contiguous slice thickness sequence. A water filled Perspex phantom with a series of partitions was scanned first without the magnet and then with the magnet suspended in the centre of the phantom. CT images taken without and with the magnet are shown in Figure 4.9.

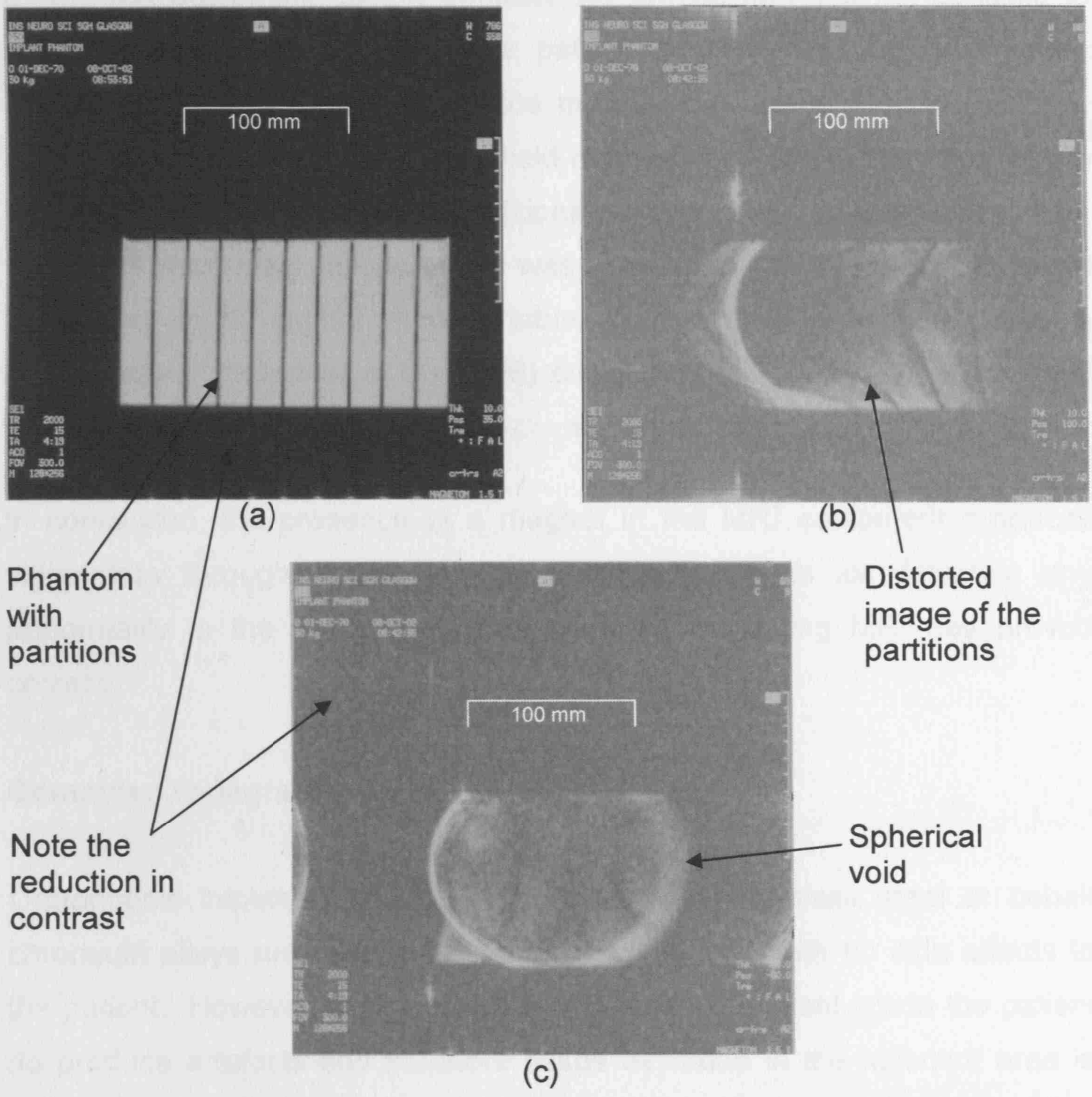


Figure 4.9 MRI images of the phantom; (a) Without magnet showing clear margins in between the partitions, (b) With magnet partitions are visible but distorted, (c) With magnet showing a spherical void of approximately 160mm diameter.

In the absence of a magnet the image is quite clear showing all partitions of the phantom, but with the magnet present there is a massive signal drop-out indicated by a much whiter field throughout the entire volume. Also there is a spatial distortion in the image indicated by curvy partitions and the image of the phantom outside its actual volume (not shown here). There is at least an artefact as far as 150mm from the magnet.

It was considered unnecessary to verify the forces generated on the magnet by the MR equipment, simply because we proved that it is not possible to utilise the MRI scanner once the patient is implanted with a magnet. However on two occasions when the magnet was taken into the scanner, large forces were felt as the hand-held magnet was taken in and out of the scanner. Coupled with this, additional forces were generated by high frequency secondary pulses and it was postulated that these forces might make very young patient uncomfortable. There is also the possibility of a heating effect (Drescher *et al.*, 2006) caused by the time varying magnetic field interacting with the magnet, which may be noticeable to the patient.

In conclusion, the presence of a magnet in the MRI equipment produces signal loss throughout the volume, making it useless for detecting any abnormality in the tissues. The concern for not using MRI has proved correct.

Computer Topography (CT)

Orthopaedic implants constructed from titanium, stainless steel or cobalt chromium alloys are successfully scanned using CT with no side effects to the patient. However, scans obtained with a metal implant inside the patient do produce artefacts and therefore tissue definition in the adjacent area is compromised. With improved algorithms, equipment manufacturers have obtained better images with minimal interference from metal objects but they are still not without artefacts. Artefact is created by metal density that is beyond the computational capability of the scanner.

The magnet was expected to react in the same way with additional distortion caused by the magnetic field. To test this, using dry human bones, a magnet was placed tightly inside a femoral intramedullary cavity close to the knee joint with an orientation similar to that of an implant magnet. The femoral condyles were then placed articulating with a tibia to mimic a knee joint and a section of a femoral diaphysis was placed alongside the articulated knee to see how far the disruption would extend. The bones were then CT scanned as normal using a Picker PQ6000 scanner with 120KV at 10mm increments. The CT data was then processed using MIMICS imaging software supplied by Materialise, Leuven, Belgium. The images are shown in Figure 4.10.

Considering the magnet was only about 16mm in diameter and 5mm in thickness, it had a significant effect on the imaging. Usually, when a large solid head such as big cobalt chromium humeral head is present, this kind of

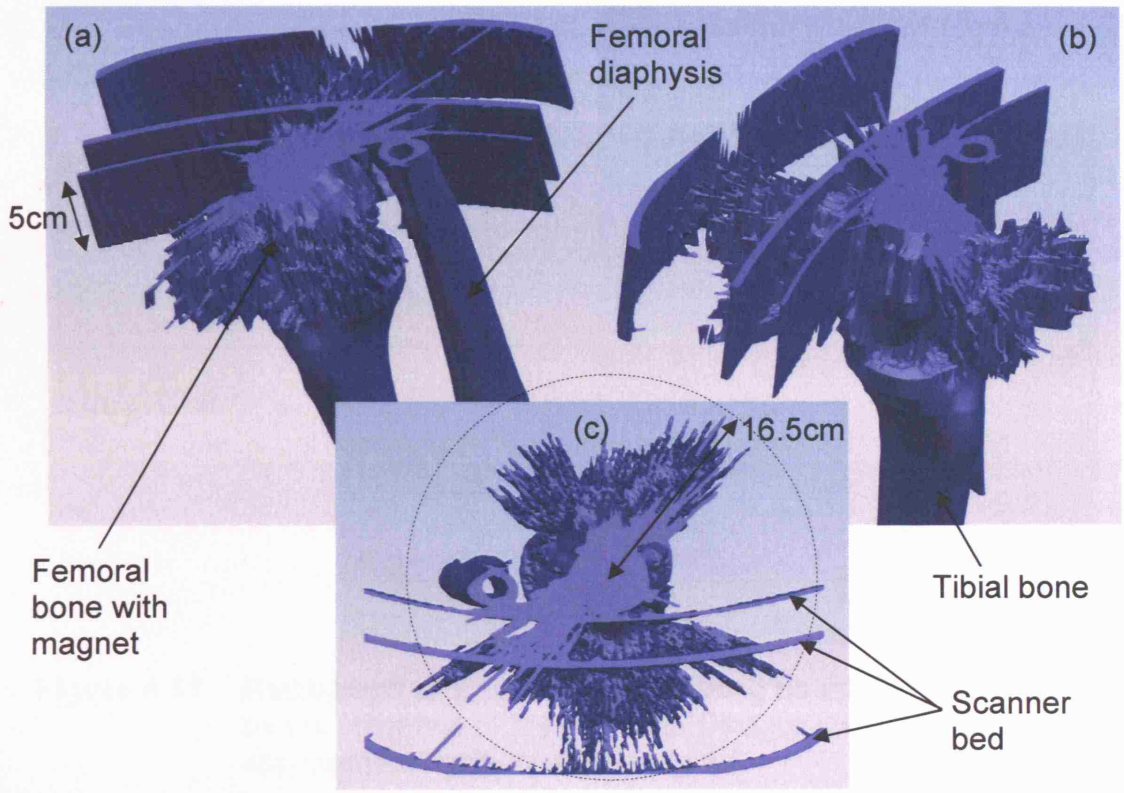


Figure 4.10 CT images of dry bones containing an implant magnet inside the femoral condyles; (a) Shows how the femoral diaphysis placed close to the joint had a minimal effect, (b) Shows the artefact penetrating the cushion reaching the base of scanner, (c) Shows the radiating effect caused by the magnet.

effect is observed. There did not appear to be any specific pattern indicative of a magnetic field and the radial artefact was similar in shape to that produced by a normal metallic object. In general, the affected area was about a 5cm thick section normal to the femur with about a 330mm diameter radial spray. Although within the affected area clinical assessment was not possible, the remaining images were unaffected.

Radiographs:

Clinical assessment using normal radiographs is widely used for a vast array of medical conditions because this method of imaging is quick and relatively safe. Fortunately, the presence of a magnet did not produce any detectable artefacts on the radiograph as shown in Figure 4.11. The patellar and the top of tibia were clear as they would be in a radiograph with a normal prosthesis.

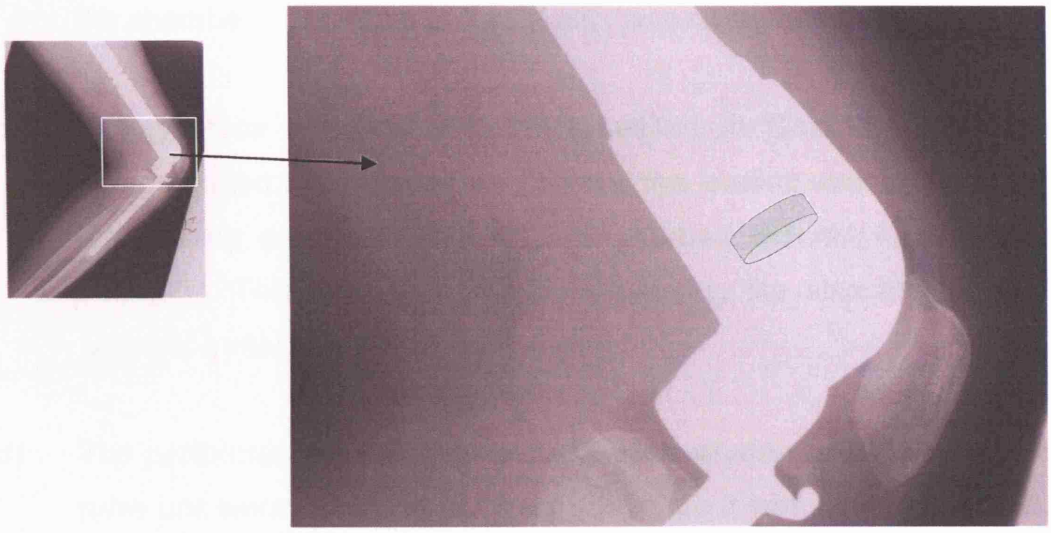


Figure 4.11 Radiograph of a distal femur showing no interference caused by the presence of the magnet. Circular disc represents approximate position of the magnet.

4.7 Discussion

In conclusion this study has demonstrated that:

(a) The telescoping section with a 13mm spigot in clinical use had a negligible number of mechanical complications. Therefore with a spigot larger than 14mm no failure should be expected unless under extreme conditions. The screw used to telescope the section had no design related failures and therefore a 7mm screw was considered adequate for the application.

(b) The gearbox output shaft seals showed no leakage for a short test period of 1.7 million cycles. The only criticism against this test is that there should have been more precise monitoring of the water vapour and condensation in a closed chamber at body temperature. The water vapour can penetrate through the silicon O-rings without leaving any trace at the seals and this may produce accumulation of water in the chamber. The effect of this, if any, was not determined.

(c) The gearbox performance was assessed in Chapter 3. It was demonstrated that in order to withstand the loading exerted during the lengthening procedure, the original gearbox did not have enough strength. This was overcome by increasing the size and by using stronger metal with low friction coating.

(d) The performance and the practicality for everyday use of the external drive unit were assessed in Chapter 3 where it was demonstrated that the unit was too large, complicated and had a very inefficient construction and implant coupling. This was overcome by using a compact laminated coil construction requiring no cooling, which was a lightweight, single phase device capable of use with ease almost anywhere.

(e) The performance of the complete device was tested with a simulated loading regime over 4 million cycles and by extending 10 times at regular intervals using magnetic coupling. There were no complications during this test.

(f) The safety and compliance of the external drive unit was achieved and the theoretical analysis demonstrated that the EMF levels were well below the recommended maximum for uncontrolled use of the device. However, it must be stated that the EMF must be assessed carefully during any further development since there is only a limited margin before the safe limit is liable to exceed.

(g) The effect of the magnet inside the prosthesis for medical diagnosis using MRI, CT and normal radiographs was assessed. It was demonstrated that the MRI imaging process is significantly affected by the presence of a magnet, making it totally unusable. The concerns were that since the MRI principle is to detect magnetism, it is unlikely that it will ever evolve to compensate for the magnetic material used in the prosthesis. For this reason, a patient who has a prosthesis containing a magnet is not permitted to receive an MRI scan. CT also showed a massive interference in proportion to the actual size of the magnet. Usually, a scan taken a fraction of a centimetre from a non-magnetic metal object is clear. With the magnet, the effect was felt over 2cm axially from the magnet, beyond which the images were normal. In the region of the magnet, scans showed radial artefacts similar to, but larger in size, than a metal prosthesis. This limits the medical diagnosis in the vicinity of the magnet but it is safe to CT scan a patient. On the other hand, normal radiographs were unaffected by the presence of a magnet and the outline of the prosthesis was normal.

The result presented in this chapter satisfies the project aim listed in paragraph 1.6, (A), (b), last bullet point [Chapter 1, page 48].

CHAPTER 5

CLINICAL USE AND RESULTS

5.1 Introduction

Pre-clinical testing can provide confidence in the clinical use of new devices and designs. However, only clinical trials can prove the effectiveness of new developments. For this reason it is important to follow-up the non-invasive growing prosthesis in patients. The device developed has two parts: the prosthesis with a sensitive drive mechanism and the external drive unit that couples with the prosthesis remotely and provides enough power to extend the prosthesis. Once inserted the prosthesis is surrounded by body fluids and tissues. With time the forces exerted on the implant can change by the changes in tissue environment through remodelling and by recovery/change of lifestyle of the patient. The drive unit has practical issues in terms of transport and the effectiveness of extending prostheses inside the patients in relation to implant location and size of the patient.

At the initiation of the project ethical approval was obtained to implant this device in a small number of patients. It is worth noting that since the introduction of this new implant, the device has evolved through minor design changes in direct response to the performance observed in the initial clinical trial. Therefore, latter devices have had better performance than those used in the initial trial. This chapter is divided into two sections: the initial trial and the additional clinical experience to the time of writing, both providing in depth insight to the device performance.

5.2 Initial trial

The aim of this initial study was to implant non-invasive growing prostheses in either the femur or tibia in up to six young patients with bone tumours requiring reasonable size resection of the bone, and to monitor the extension of the device over a period of up to two years.

Ethical approval was obtained from the Ethical Committee at the Royal National Orthopaedic Hospital NHS Trust to implant up to six devices over a period of one year and then monitor them for a further one year.

5.2.1 Risk evaluation

In the absence of this new implant, these patients would have been treated with a minimally invasive extendible growing prosthesis. This new implant has obvious benefits over the old device, as the patient no longer requires an operation or stay in hospital and therefore the risk of infection and trauma to the patient is greatly reduced. Although, the initial cost of the implant is much higher than the conventional device, the cost of patient treatment is greatly reduced as no surgical intervention is required to extend the prosthesis. The new procedure can also be carried out almost anywhere, taking only few minutes.

The risks are that the implant could malfunction by internal component failure or by inability to use the external drive for some clinical reason. If an implant failure occurs, then the complications are greater. In the minimally invasive device, as the assembly is much simpler, malfunction of the drive system can often be rectified by simply replacing one half of the telescoping section and thereby not affecting the original fixation of the prosthesis. With the new device, which is much more complicated, this option is not available and therefore the whole prosthesis would require replacing, causing destruction of fixation and possibly loss of bone.

Testing and device handling in the laboratory gave confidence that the expected benefits to the patient and the improvements in the quality of treatment outweighed the risk of device malfunction and the risks were considered very small in a short clinical trial. The only drawback with this short trial is that it will not identify any long-term complications. Once the implant has been inserted, it will remain in place unless the device fails, or it is fully extended, or the patient does not survive.

5.2.2 Patient selection and implantation

As construction of the prosthesis is time consuming and complex, six telescoping sections complete with gearbox were constructed all with the capability of 60mm extension. They were tested in advance for function. On selection of a patient, a telescoping section was then incorporated in a custom prosthesis made for that patient. A single Mk2 drive unit, shown in Figure 5.1, was constructed to extend these prostheses.

Figure 5.1 Mk2 drive unit with isolating transformer.

Chapter 2 implied that the majority of juvenile tumours occur in the distal femur and proximal tibia. The size of the telescoping section also required that patients were suitable for a medium size knee replacement and a minimum resection length of 155mm from the joint line. Based on these criteria, patients were selected as they became available, restricted only by their age and resection level. These implants were manufactured as custom-implants by Stanmore Implants Worldwide Ltd and supplied in sterile condition for insertion. A typical distal femoral replacement is shown in Figure 5.2. All implants had normal external appearance with the extending

mechanism embedded in the implant shaft. As the implant contains a magnet that can lose some of its magnetism at elevated temperatures, these implants were sterilised by gamma irradiation instead of normal steam sterilisation prior to insertion. Prostheses were inserted through a conventional surgical approach requiring no special handling precautions.

In the patient group there were 3 male and 2 female primary tumour cases with an average age of 12.3 years, ranging from 10.3 to 14.4 years. The sixth patient was a fully grown male aged 18.9 years, who had over 9cm of limb length discrepancy as a result of a previously failed arthroplasty. The proposal for this patient was to restore the limb length discrepancy post-operatively over the next few months and then at the end of restoration, replace the growing prosthesis with definitive adult type prosthesis. For this reason the implant was inserted without bone cement or HA coating. These were all distal femoral replacements with an average length of 227mm ranging from 180 to 265mm, which is almost 2/3 of the femur.

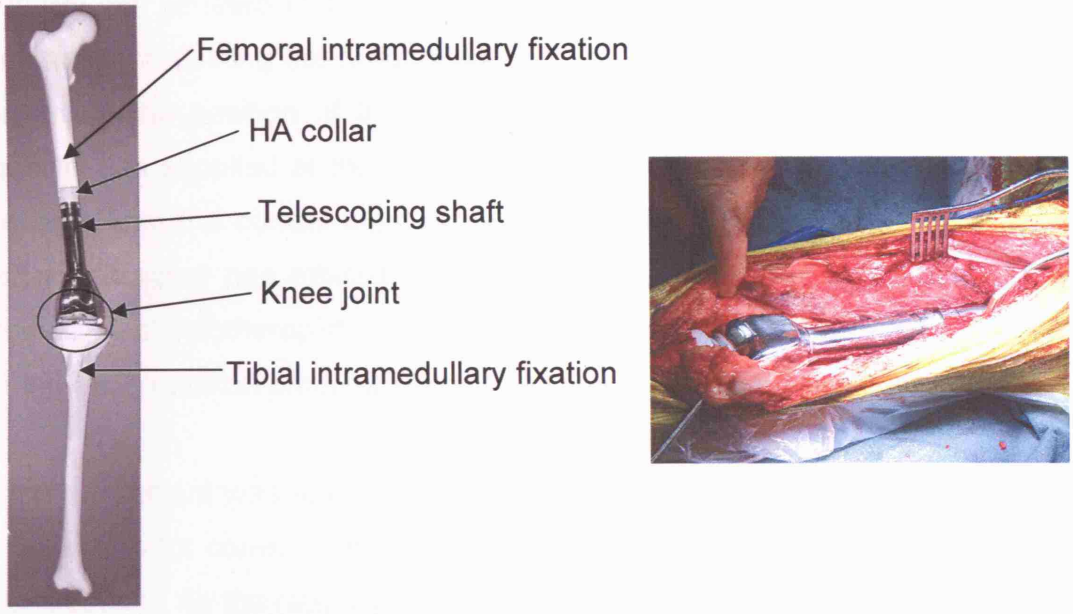


Figure 5.2 A typical non-invasive growing distal femoral replacement incorporating a knee joint, shaft of the prosthesis and a HA collar. The femoral and tibial fixation is achieved intramedullary.

5.2.3 Lengthening procedure

Patients were allowed to recover from the operations before extension sessions were arranged. It is worth noting that due to side effects of chemo- and radiotherapy, growth rate is often reduced and therefore in some patients there is a long delay before an extension session is required.

Patients were regularly assessed in out-patient clinics for general post-operative recovery and limb length inequality. When the limb length discrepancy was appropriate, the patients were x-rayed to determine the implant length before extension. Also the range of motion of the knee was assessed qualitatively. It was stipulated that the implant should not be lengthened if the range of motion at the knee could not achieve full extension with a minimum 90^{o} flexion. This is because soft tissues tighten as the implant is lengthened resulting in a stiffer knee which is considered detrimental to patient recovery.

After examination, patients were asked to place the affected limb through the external coil situated in the out-patient clinic, ensuring that the part of the prosthesis containing the magnet was placed approximately in the centre of the coil. The position of the magnet is clearly marked on the prosthesis specification supplied at the time of operation. It is also important to place the limb from the correct side of the coil marked "Front" in order to ensure that the magnet has rotated correctly. Failure to do so may reverse the growth. A physiotherapist or a nurse was present to ensure patient comfort during the extension process and to identify any abnormal reactions.

Once the patient was ready to receive an extension procedure, the coil was switched on for correct field rotation as indicated on the prosthesis insertion specification. As the rate of growth in the telescoping section is predefined at 0.25mm per minute, the growth was simply timed. From the onset it became clear that when the implant magnet was spinning it created an audible sound which allowed the operator to ensure the implant was extending. As described in Chapter 3, a stethoscope was used to enhance hearing. At the

end of the process the coil was switched off, the range of motion at the knee reassessed and the patient was allowed to walk immediately after the session.

After extension, patients were retained in the outpatient clinic for at least one hour during which time another radiograph was taken. This procedure was followed for first few extensions and when enough experience was gained, radiographs were taken only when required.

5.2.4 Result

The data collected for all six patients is tabulated in Table 5.1 and the cumulative extension is shown in Figure 5.3.

Patient (Sex/Age)	Extension No.	Date of extension	Days since implanted	Range of motion				Amount of Extension (mm)	Motor operation	Comments
				Extension		Flexion				
				before	after	before	after			
P1 (F/13)	Operation date - 27/11/2002 - Primary									
	1	08/01/2003	41	180	180	80	95	4	ok	-
	2	12/02/2003	75	180	180	60	70	4	ok	Patient had a fall two weeks before
	3	28/05/2003	181	-	-	-	-	0	ok	Not extended but checked for function
	4	08/10/2003	311	-	-	-	-	0	ok	Not extended but checked for function
P2 (F/10)	Operation date - 14/04/2003 - Primary									
	1	02/07/2003	78	180	180	60	60	4	ok	-
	2	08/10/2003	174	180	-	60	-	0	Not turning	Gearbox would not respond
	3	22/10/2003	188	180	-	50	-	0	ok at higher power	Limb 5mm longer. Not extended but checked for function
P3 (M/12)	Operation date - 14/04/2003 - Primary									
	1	15/07/2003	91	180	180	90	90	4	ok	-
	2	02/12/2003	228	180	170	50	50	4	ok	-
	3	23/12/2003	249	180	-	90	-	4	ok	-
	4	16/01/2004	272	-	-	-	-	4	ok	-
	5	30/01/2004	286	-	-	-	-	4	ok	-
	6	09/02/2004	295	-	-	-	-	4	ok	-
	7	16/02/2004	302	-	-	-	-	2	ok	-
	8	20/02/2004	306	-	-	-	-	2	ok	-
P4 (M/18)	Operation date - 19/08/2003 - Revision									
	1	12/09/2003	23	-	-	-	-	4	ok	Sensation of vibration
	2	22/09/2003	33	180	-	150	-	4	ok	No sensation this time
	3	26/09/2003	37	170	150	110	120	4	ok	Before extensions patellar subluxation occurred but not since
	4	29/09/2003	40	180	180	140	140	4	ok	17mm extension confirmed by x-ray
	5	03/10/2003	44	180	180	135	145	4	ok	-
	6	06/10/2003	47	180	175	140	150	4	ok	Hamstring stretching
	7	10/10/2003	51	180	175	135	145	4	ok	Little stiff after extension
	8	13/10/2003	54	180	175	135	135	4	ok	Two lots of 2mm with 5 minute rest in between due to stiff feeling
	9	17/10/2003	58	180	170	135	150	4	ok	Felt hamstring pull after last extension but ok now
	10	24/10/2003	65	175	170	135	140	4	ok	-
	11	27/10/2003	68	175	170	-	140	4	ok	Slight discomfort when internally rotated
	12	31/10/2003	72	175	170	135	140	4	ok	-
	13	07/11/2003	78	175	160	135	135	4	Stopped once - ok	Pins and needles in the lower part
	14	17/11/2003	88	175	170	134	135	4	ok	Tingling in hamstring last week but ok now
	15	21/11/2003	92	170	165	135	140	4	ok	Full extension and 120 flexion before extension during physiotherapy prior to extension but not when extended
	16	26/11/2003	97	170	165	155	155	4	ok	-
P5 (M/11)	Operation date - 03/11/2003 - Primary									
	1	06/02/2004	93	-	-	-	-	4	ok	-
P6 (M/14)	Operation date - 02/02/2004 - Primary									
	1	07/04/2004	65	-	-	-	-	4	ok	-
Total	29	Extensions					Total	112	mm	

Table 5.1 Patient data collated for the initial clinical trial conducted on patients requiring customised distal femoral growing prosthesis.

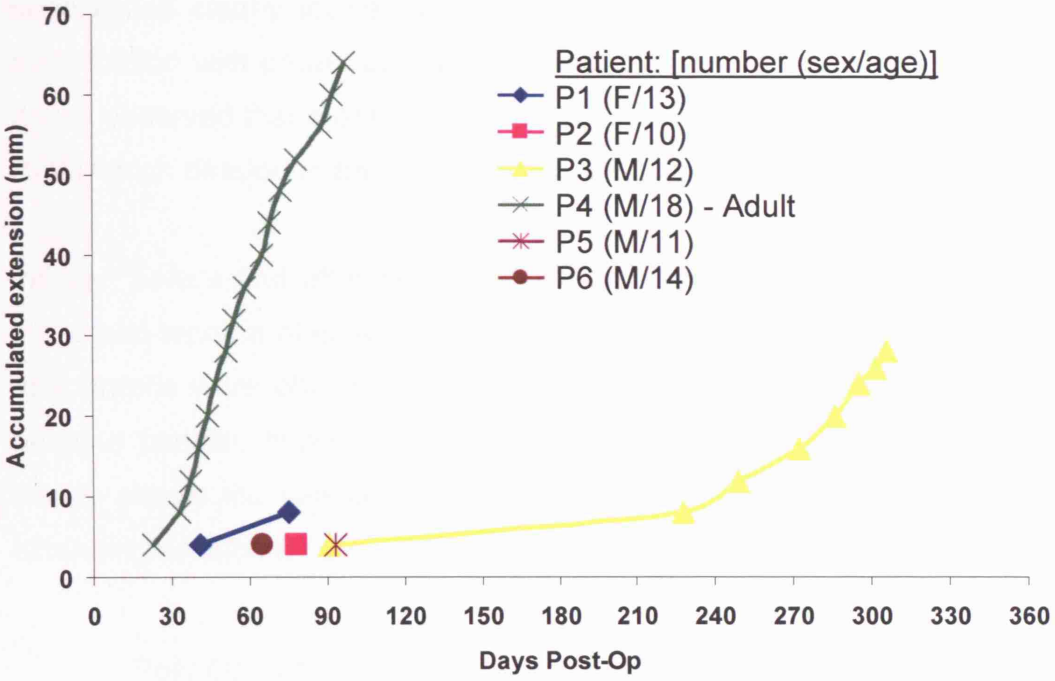


Figure 5.3 Cumulative extensions subsequent to the prosthesis insertion for each patient.

Only two out of six patients had more than two extensions performed during the first year post insertion, as seen in Figure 5.3. The other four patients either had one or two extensions or only the gearbox was tested to ensure the implant was functioning properly (Table 5.1). However, overall a total of 29 extension sessions were performed giving a total of 112mm of extension. A growth of 64mm was achieved over a short period of 74 days, for the 18 year old patient with limb length discrepancy. This patient also suffered from other complications such as patellar subluxation, hamstring stretching, knee stiffness, pain from internal rotation, pins and needles and tingling from time to time. It is not entirely clear if any of this was directly related to the rapid extension, as the discomfort was relatively short and there were no cumulative and long-lasting effects observed.

Although it was initially stipulated that a range of motion (ROM) from full extension to 90° of flexion was permitted, the revision case had an initial limited ROM and this might have resulted in the short-term complications. The primary cases in this group had none of these problems. This

observation clearly indicates that the rate of growth must be planned, in combination with proper and regular clinical assessment with physiotherapy. It was observed that a 4mm extension caused approximately 10° reduction in ROM which needed to be regained before the next extension.

Initially "before and after treatment" radiographs were obtained to establish the actual amount of extension produced during a procedure. Later very few radiographs were obtained since the audible sound of the running gearbox became familiar, indicating that the prosthesis was expanding. Figure 5.4 clearly shows the telescoping shaft before extension and after the second extending session for patient F1.

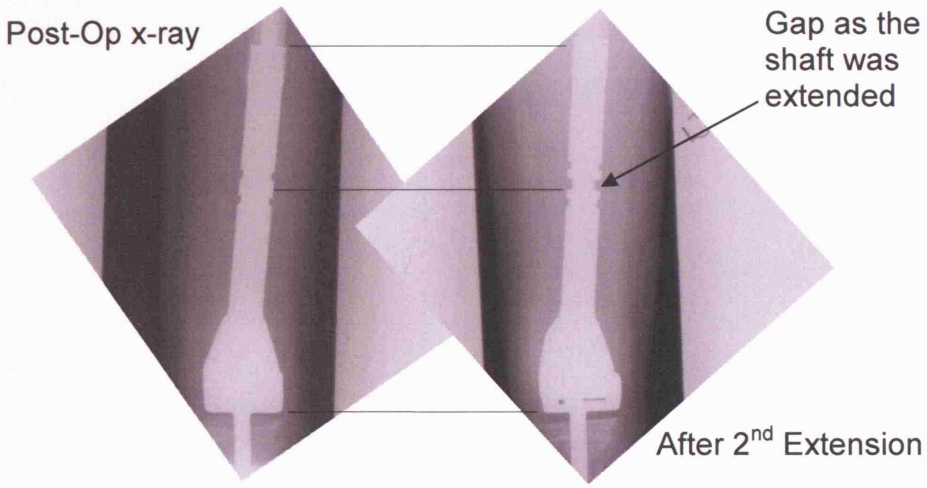


Figure 5.4 Typical radiographs showing before and after lengthening session.

During the 15 to 20 minute extension process, the patients felt no major discomfort. The limb was allowed to move within the coil a little, but the shape of the box made it difficult to straddle between the legs. No uncomfortable feelings from vibrations were reported, even though all of the patients felt some faint vibrations. There was no accumulation of heat during the 20 minute session.

On two occasions there was a mechanical hesitation for the motor to pick up speed. This was overcome in one case by repeated restarts and in the other case the coil-strength was increased. Although the second case was never extended any further, the first showed no signs of hesitation after the initial faltering.

5.3 Wider clinical experience

A wider clinical experience was gained between November 2002 and April 2005 when 26 patients were treated using this new implant. The purpose for this analysis was to assess mechanical and electrical complications relating to the new invention.

In this group there were 22 juvenile patients between the age of 6 and 17 years with a mean age of 11 years, and 4 adults between 18 and 61 years with a mean age of 41 years. Please note that this group includes six patients evaluated in the initial trial. There were 14 male and 12 female patients. One of the older patients, the 18 year old was fully extended and was revised with a second similar implant for further growth, making a total of 27 implants. In terms of skeletal sites there were 4 proximal tibial, 17 distal femoral, 2 proximal femoral and 4 total femoral replacements. There were 18 primary and 9 revision cases with follow-up ranging from 0.1 to 28.1 months, with an average of 12.6 months. Of these 27 implants 17 were extended, 1 was too large for the coil due to oedema and 9 were yet to be extended.

One single patient felt discomfort during an extending session caused by tissues stretching and the extension was reversed to relieve the symptoms. This patient had no further complications at subsequent lengthening sessions. Four patients had persistent reduced range of motion at the knee, but were allowed to extend steadily. Two patients died due to disseminated carcinomatosis.

In this cohort 69 extensions were performed, giving a total of 309mm growth with an average extension per session of 4.5mm. Some patients received as much as 10mm extension in one session. As one would expect, large resections such as total femur were able to receive a large amount of extension in a session. For short resections, the adjacent tissues can only accommodate a limited amount of stretch. Therefore, when planning an extension the length of resection, the range of motion and the patient reaction during the procedure must be take into consideration.

The mechanical complications in the explanted devices were assessed as described in Appendix A. Although there were only three devices that were explanted, these provide a unique insight into the durability of the growing mechanism. In general, 1 was fully extended and was replaced by a longer similar device, 1 patient had recurrent disease and had the limb amputated and 1 implant extended well for about 40mm and then seized up and was replaced with a new identical implant. The conclusion of this assessment is that there were no mechanical complications with the gearbox or the drive unit in these devices. The seized implant had a gooey deposit on the screw and the shaft of the prosthesis that was preventing the implant from being extended. Once the bond was broken during a laboratory test, the implant worked well showing no hesitation under load. It was decided that if this were to happen again in the future, a proper assessment would be conducted, by obtaining a biopsy sample adjacent to the implant and a sample of the deposit on the prosthesis for histological assessment.

5.4 Discussion

For the treatment of bone tumours in juvenile patients, the usual practice is to replace the diseased bone with a conventional implant that usually requires invasive surgery to extend the prosthesis. This new device removes the element of repetitive surgery, greatly improving patient comfort and the cost of treatment. Amongst this small number of patients the implant has proved a huge potential, not just for juvenile patients but also for older patients who have limb length discrepancy due to previously failed arthroplasty.

When presented with a choice between the old invasive device and this new non-invasive device, patients prefer the new device even though the long term effects are unknown. It is important to remember that these patients have had cancer and that they are undergoing chemotherapy. Consequently growth of the implant is of secondary importance to them. Also, the initial surgical procedure is similar to that for a conventional implant, hence adding no additional complications. Therefore, the only part of the performance that we can evaluate is the process of extending the device in the patient.

Seventeen implants were extended between November 2002 and April 2005 and all together 69 extension sessions were performed giving a cumulative growth of over 0.3 meters. This possibly saved over 30 operations which would have been performed with the old device. All patients were able to walk as before immediately after the treatment. There were several complications, but all of these were resolved. Some issues remain, and these are discussed in the following paragraphs.

Soft tissues stretching:

Patients with knee replacements were functionally assessed before and after the treatment. This showed approximately 10^{o} to 15^{o} reduction in range of motion for 4 to 10mm extension, which in most patients was recovered within days. In a few patients, either lack of interest in physical exercise or due to surgical trauma, the range of motion was not recovered and a degree of fixed

flexion deformity was seen. It is therefore of paramount importance to regularly assess each patient and provide adequate physiotherapy to recover loss of range of motion every time a limb is extended, before further treatment is provided. This would minimise the cumulative joint stiffness and it would reduce the load on the implant, improving coil coupling and implant performance for its extending capability.

Magnet synchronisation:

Out of a group of 27 implants, one implant failed to extend whilst 5 hesitated to extend at some stage. This is a complication rate of about 22% which in terms of conventional surgical management of tumours using an implant is relatively high. It is clear that there is some scope to improve the magnetic coupling by increasing coil power, but there is an even greater need to improve the reliability of the gearbox. This is important as these implants are made for children who are keen to be as normal as possible, both in accepting the implant and in their activities. Without doubt this work needs to continue for the foreseeable future.

Revision options:

Generally speaking, in the evolutionary sense, the prosthetic failures caused by implant malfunction will reduce as we learn more about the mechanism and make improvements with time. However, biological failures caused by infection and/or body reaction may not be resolved and may persist. Also, as the patient grows, longer implants may be required to continue further growth. For all these reasons, implants need to be revisable over time. The most useful progression is to make the implant modular in construction, so that flexibility is built into the implant to cope with late complications. We already have seen one patient where failure of the gearbox drive made it impossible to resolve the problem.

Size of implant:

Patient selection was based on the size of the implant, which limits it to patients older than 9 to 10 years of age. There is therefore a need for a smaller device that can be used in patients as young as 2 to 3 years of age. There are two complications in very young patients: the width of the implant needs to match the bone size and the length of the implant is much smaller. However, at the same time the amount of growth is greater. This too needs further development, to make the implant smaller and stronger for these patients.

5.5 Conclusions

The implant design posed no complications to surgical management of the patients compared with the conventional minimally invasive growing prosthesis. The biggest difference in this device was the absence of further surgery in order to extend the implant. This was demonstrated in the six patients in the initial trial, where the ability for the implant to extend without complications and discomfort to the patient was confirmed. Due to the absence of surgery, it is believed that the infection rate will also be reduced which will be demonstrated in due course. This implant required more frequent but smaller increments in extension, significantly reducing the cost and at the same time vastly improving patient treatment.

One patient, who was 18 year at the time of the initial trial, had rapid extensions over a short period of time experienced complications. From this, it is clear that the rate of growth must be planned in combination with proper and regular clinical assessment of the patient taking account of previous history and the level of physiotherapy given. It was not clear if any of the complications were directly related to the lengthening process, as the patient already had a prior history of minor complications.

Although the primary cases in the initial trial showed no complications, we must not be complacent and there is a need for continual and methodical monitoring. It was observed that a 4mm extension caused approximately 10^{o} reduction in ROM and that regular physiotherapy between the extensions is important.

The implant and the extension process behaved as expected for this small number of patients. Again, due to small numbers it is difficult to determine what caused the hesitation in the gearbox. Increase in power suggests that there was either interference with the drive magnet or too much load was created by the soft tissues. On the other hand, load was not an issue with the 18 year old patient with rapid extension. A further refinement to reduce frictional losses in the gears is recommended.

The drive unit (Figure 5.1) used for the initial trial was clearly too large for the clinical staff to manipulate and for the patient to sit comfortably for up to 20 minutes at a time. There was a clear indication to make the radial thickness of the coil as small as possible. This was also recommended by the construction of a compact smaller unit shown in Figure 5.5. There were no other complications with the drive unit.

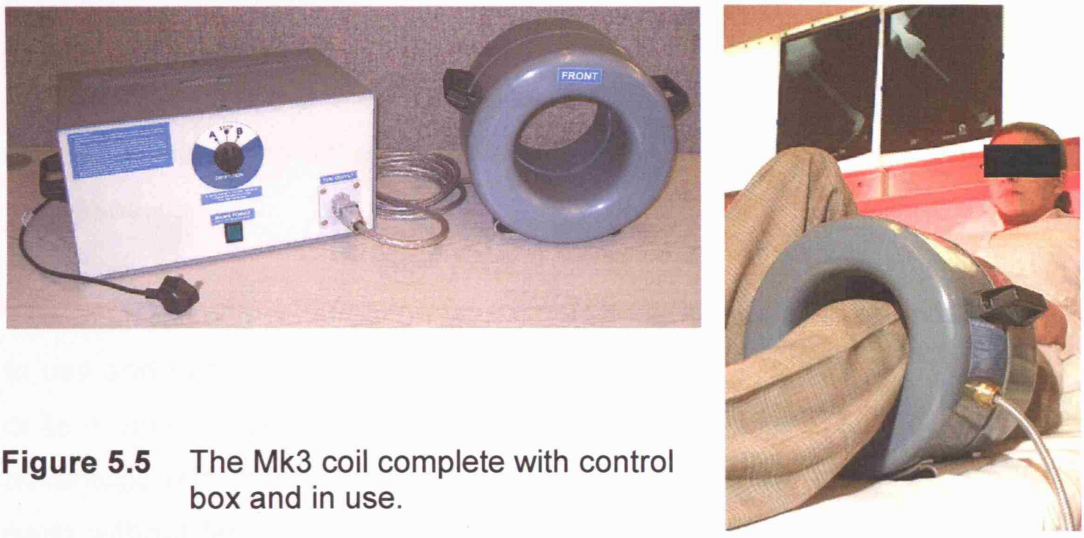


Figure 5.5 The Mk3 coil complete with control box and in use.

Looking at the wider application, unfortunately, one patient failed to extend from the onset. Several unsuccessful attempts were made and finally it was decided to increase the coil power gradually from 55 volts normal operating level to a maximum of 75 volts. Although the magnet failed to pickup the rotation even at full power, the patient felt the prosthesis vibrate. This raises two points. The vibrations may be due to the magnet which was prevented from full rotation by the implant, resulting in the torsional forces being transmitted to the body of the prosthesis and producing vibration. The coil also, as highlighted in Chapter 3, can induce eddy currents in the metallic components of the prosthesis and may cause discomfort due to leakage into the surrounding tissues. This is unlikely at this low level of magnetic flux density, which is well within the safe levels stipulated in the safety guidelines.

Therefore, the most plausible reason is probably the magnet making the implant vibrate. This implant was subsequently extended surgically by inserting a set of split collars.

The problem of the inability of the magnet to synchronise was observed in a further 5 patients. Of these, 2 hesitated at the start but then behaved satisfactorily, 1 extended hesitantly during the first two consecutive lengthening sessions but then the patient unfortunately died as a result of unsuccessful cancer treatment and 2 were able to extend at elevated coil power. This in fact showed that the patients with elevated coil power were fine provided that the magnet rotated and because of this they did not feel excessive vibrations although the eddy currents in the prosthesis may have increased.

The modified coil construction was comfortable to the patient and was easy to use and transport. With this new coil, patients were able to sit on a chair or lie down on a bed with the other limb placed next to it. The most important advantage with this is that patients were able to insert the leg right up to the groin without feeling uncomfortable. This is required for high resection in a proximal femoral replacement where the magnet is place just above the resection.

The result presented in this chapter satisfies the project aim listed in paragraph 1.6, (A), (c) [Chapter 1, page 48].

CHAPTER 6

SPINAL DISTRACTION FORCE MEASUREMENT

6.1 Introduction

Bone deformities occur in patients of all ages. These deformities are caused by neuromuscular or bone diseases, natural degenerative processes, through trauma or sometimes with no apparent reason at all, called idiopathic deformities. In most of these idiopathic conditions, there is usually nothing wrong with the bone but it simply has taken a different shape. In children, deformities are treated very effectively because the bones are still growing and are able to respond to the change in stresses imposed by the treatment, bringing them back into normal alignment. This is not true in adults since bone response is very slow. It is common knowledge that if a child with a deformity is left untreated, the child could become severely disfigured, suffers discomfort and be debilitated in later life. Therefore, it is now accepted practice to treat deformities before adolescence by utilising the body's own mechanism to help correct the deformity.

Scoliosis of the spine is a common example of an idiopathic deformity and it is believed that it accounts for almost 80-85% of all spinal cases. There are a number of techniques available to treat these patients (Bridwell, 1998; Lonstein, 2006). Spinal fusion, as the name implies, is a technique where adjoining vertebrae are fused together. It is somewhat permanent and non-reversible. Also, if applied incorrectly or at a younger age it can retard spinal growth, leaving the patient disproportionate in shape. Body-casts or body-braces are used to apply apposing bending in the spine, which works to a degree, but can be very uncomfortable for the patient to wear. Also, as with artificial limbs, as the patient grows and changes in posture these devices require replacement relatively frequently to fit the changing conditions.

A more drastic approach to treat spinal deformity is to use straighter rods which are attached to the bent spine, pulling it in a straightened configuration. This is fine for marginal deformity, possibly at the onset of the disease. However, at more advanced stages, as discussed in Chapter 1 and shown in Figure 6.1, one or two rods are required, anchored at top and bottom of the margin of the deformity and then by extending the gap between the anchor

points, this spine is thus straightened. This lengthening process is done gradually over a period of several months by surgical intervention. Over the past four decades surgeons have used spinal rods for the treatment of these patients with a reasonable rate of success. The advantage with this technique is that it does not affect the natural growth of the child and at maturity it can be removed, either without further treatment or in some cases after spinal fusion to hold the spine in place. The biomechanics of spinal deformities is very clearly defined by Schlenk *et al.* (2003) where the authors have described the clinical relevance of the deformity with that of the corrective procedures.

With any invasive technique there is a high risk of infection every time the patient has surgery and over the lengthening process, which can last for 2 years, there is great trauma for the patient. Experience gained from bone tumour cases convinced us that the best solution for these patients is to use a non-invasive means of lengthening rods. However, in order to build such a device peak loads during the lengthening process needed defining. In association with surgeons at the Royal National Orthopaedic NHS Trust and Great Ormond Street Hospitals, *in vivo* distraction force measurements were taken from a small group of patients who were receiving lengthening procedures. The method used and the outcome of the result is discussed in this Chapter.

6.2 Measurement method

Fortunately, not many children with spinal deformity are being treated at any one time and there are a number of different types of rod systems that are available for surgeons to choose from. To provide a consistent result it is better to evaluate patients with comparable implants. As it happens, at these hospitals only "single rod" or "two rod" systems are in use. A typical

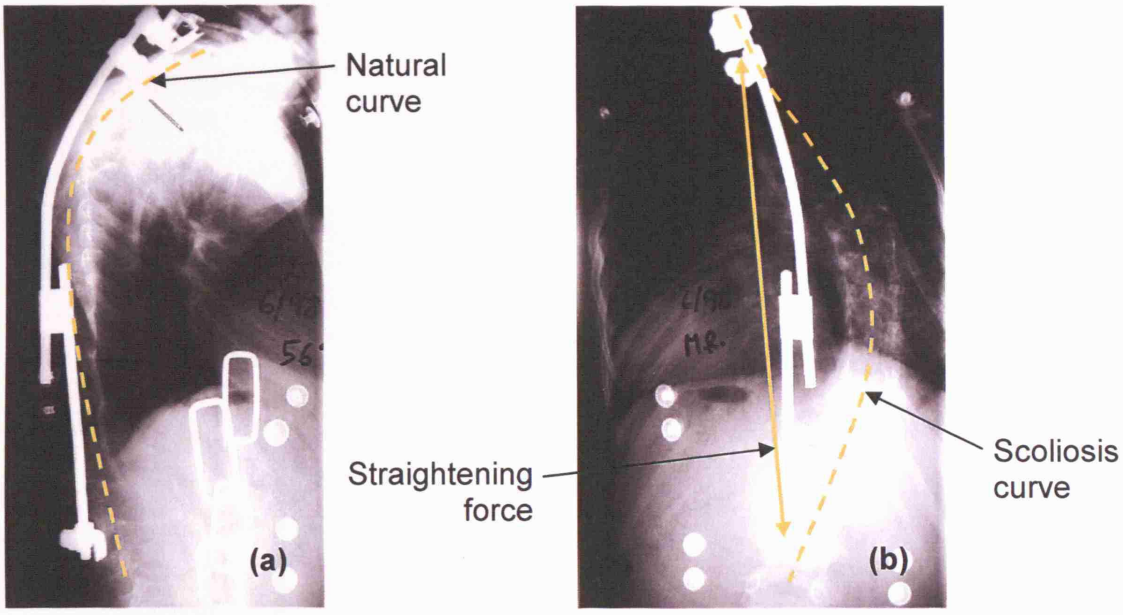


Figure 6.1 A scoliosis patient treated with a two rod system.
(a) Sagittal plane, (b) Coronal plane.

application of a two rod system is shown in Figure 6.1, where one rod is fixed at the upper thoracic level and the other at the upper lumbar level with a coupling block called a "domino" joining the two rods in the middle. The rods are bent to conform to the natural spinal curve in the sagittal plane, but they are maintained straight in the coronal plane acting as a column supporting the collapsing spine. Periodically, through surgery, the domino is unlocked and is pushed along the rod, forcing the two fixation points apart. It is then locked in the new position, straightening the spinal column.

A schematic of the rods and extending instruments are shown in Figure 6.2. First a detachable rod clamp is fitted to one of the rods close to the domino,

with enough gap to get an expander tool in between the clamp and the domino. The expander tool is then located in position and the two locking screws are unlocked before forcing the domino along the rod. Once the desired extension is achieved, the domino is locked again before removing the instruments. The procedure is repeated for the second rod in the same way.

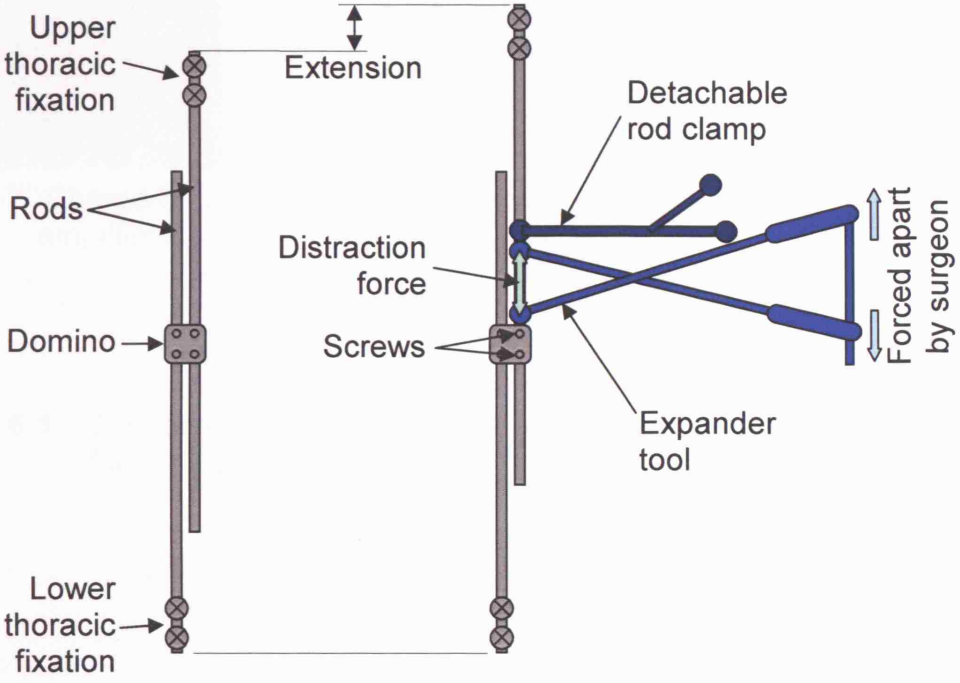


Figure 6.2 Schematic of the growing rods and the instruments used in lengthening two rod system.

In order to measure the distraction force, an instrumented expander tool was constructed which incorporated a load-cell to allow force measurement at the tip of the jaws and a scaled graduation in millimetres, to indicate the displacement. The device was designed to be autoclaved and had a cable long enough to connect to a charge amplifier placed remotely from the sterile conditions around the patient. The output from the charge amplifier was recorded on a laptop. As there was no direct electronic displacement output from the expander tool, the force was recorded only when the surgeon

indicated at 1mm increment. The expander tool together with the charge amplifiers are shown in Figure 6.3.

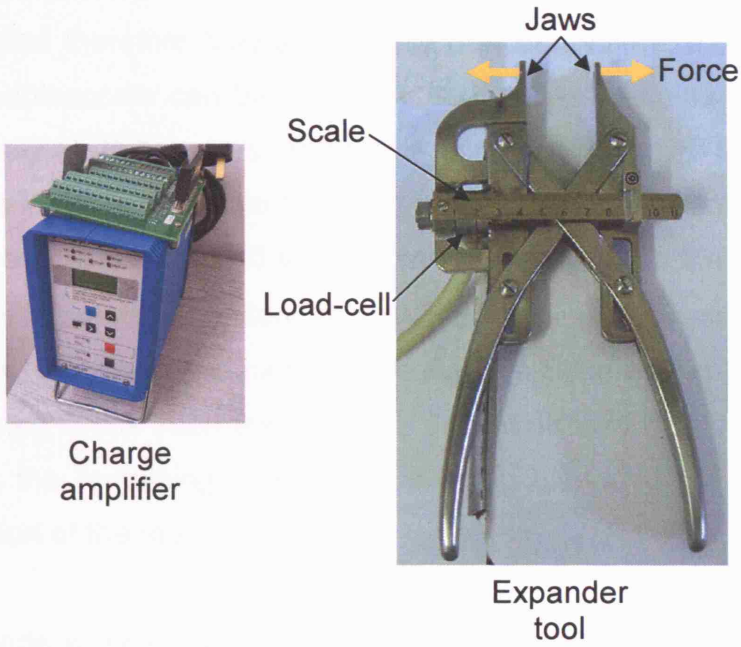


Figure 6.3 Expander tool and the charge amplifier used for the distraction force measurements.

Digital output from the charge amplifier was sampled at 10Hz. The expander tool was load tested for up to 1000N and had a repeatability of better than 4% of the full-scale deflection, and a Pearson product moment correlation coefficient (R^2) of 0.989. However, the accuracy of the displacement measurement was very crude, using a ruler in a surgical environment, and was judged no better than ± 0.25mm.

6.3 Patient selection and method

Generally children are classified as infants (up to 4 years), juveniles (4 to 10 years) and adolescents (10 to adulthood). Infants are too young to surgically treat and therefore they are usually provided with external aids. Juveniles and adolescents can be surgically treated. As explained previously, due to the rarity of these cases, at the time of this study only 6 patients (3 male and 3 female) were available to undergo distraction treatment. The average age of these patients was 10.4 years, ranging from 6.2 to 13.1 years. Five of the patients had double titanium Colorado® spinal rods supplied by Sofamor Danek Group and one had a single titanium Synergy® spinal rod, supplied by Interpore Cross International. One patient already had a previous extension, whilst the remaining patients were being extended for the first time since insertion of the rods.

The rods were implanted as part of a routine treatment and in accordance with the manufacturer's specifications. After implantation the patients were kept in moulded plastic braces until a distraction procedure was required.

With the patient under general anaesthesia and laying flat, the domino and rods 50mm either side of the domino were exposed through a centralised skin incision. A detachable rod clamp was then securely attached to one of the spinal rods close to the domino, leaving enough gap for the expander tool. The expander tool was then located in position and two locking screws on the domino were loosened, allowing the expander tool to take the initial load. The domino was then pushed along the rod by 1mm and momentarily stopped at that point to record the load. This was repeated in 1mm increments until the desired extension was achieved and the corresponding loads recorded. The domino was locked in the final position before removing the instruments. The same procedure was repeated for the second rod and for the single rod system in one patient. It was accepted that approximately a 10 second dwell allowed at each 1mm increment to record the load would allow viscoelastic flow in the soft tissues (Duffy *et al.*, 1994) before extending further. Although, this would stress-relieve the tissues as the extension

progresses, reducing the overall peak load, it would provide a good indication of the loads associated with extension procedures. Thus, force profile measurement for each rod took no more than about one minute before the domino was locked in place.

6.4 Results

The details of the extension sessions and the amount of extension for each patient are shown in Table 6.1. The loads recorded in Table 6.2 for all patients are represented graphically in Figure 6.4. One patient had already had a previous extension, whilst the remaining patients were extended for the very first time since the insertion of the rods. Where the two rod system was used, forces in both rods were recorded separately. These measurements were taken over a period of 20 months. There were no instances of fracture of the posterior vertebral elements or instrument failure during or after distraction.

Patient No.	D.O.B.	Gender	Extension No.	Date extended	Age at extension	Distraction (mm) Total for session (Rod^1 + Rod^2)
1	01/05/1992	Male	1	22/04/2001	9.0	21 (11 + 10)
			2	22/07/2002	10.2	22 (12 + 10)
2	01/11/1990	Male	1	08/05/2002	11.5	17 (7 + 10)
3	04/03/1996	Female	1	15/05/2002	6.2	10 (single rod system)
4	01/06/1989	Female	1	01/07/2002	13.1	12 (6 + 6)
5	01/02/1990	Male	2	19/08/2002	12.6	23 (11 + 12)
6	!	Female	1	20/11/2002	!	22 (12 + 10)

Table 6.1 Details of extension sessions and the amount extended each time.

Ext. mm	P1-1/1	P1-2/1	P1-1/2	P1-2/2	P2-1/1	P2-2/1	P3-1	P4-1/1	P4-2/1	P5-1/2	P5-2/2	P6-1/1	P6-2/1
1	106.1	160.0	281.8	250.5	65.2	31.4	227.2	160.7	161.4	83.5	393.8	66.4	74.6
2	133.3	204.2	500.0	300.8	72.1	307.3	256.9	248.2	224.7	155.9	356.6	72.7	84.4
3	167.3	219.5	563.3	371.3	218.1	377.3	278.5	268.9	215.1	216.9	437.2	85.3	131.6
4	195.5	267.9	585.8	416.2	268.9	451.1	298.2	454.3	286.6	260.6	355.8	95.7	191.9
5	202.3	325.2	563.4	473.9	365.1	477.0	379.3	418.3	294.8	359.7	387.1	97.5	220.9
6	238.4	431.7	567.6	485.3	454.8	500.4	430.4	695.9	321.4	347.1	431.6	125.6	352.7
7	301.9	509.5	541.0	490.8	511.3	515.6	454.3			394.0	428.6	160.2	377.7
8	333.0	526.9	456.1	495.4		555.6	519.5			413.5	267.6	170.4	419.5
9	383.5	564.1	470.7	526.8		580.2	561.9			487.5	499.5	223.2	452.4
10	483.4	625.2	531.9	546.4		591.9	583.6			548.4	435.2	234.3	463.5
11	479.7		535.2							561.1	471.2	274.5	
12			626.0								594.4	315.8	

Table 6.2 Force measured in each rod.
(Key: P4-1/1 = Patient 4, rod 1, first measurement)

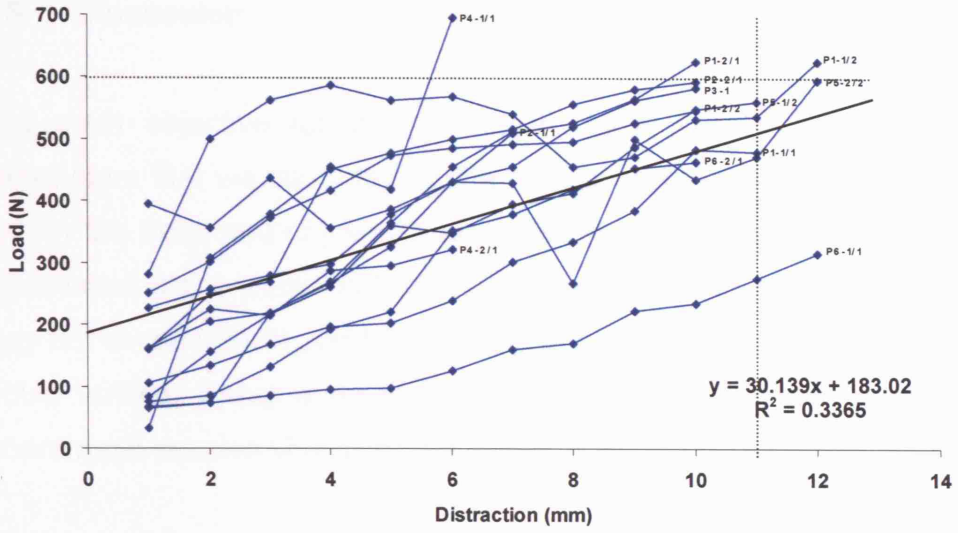


Figure 6.4 Measured loads in all six patients in all rods with overall regression line.
(Key: P4-1/1 = Patient 4, rod 1, first measurement)

Amongst these patients at 1mm extension, force ranged between 32 and 394N with a mean force of 159N (n=13). At 12mm the force ranged between 316 and 562N with a mean force of 512N (n=3). In one case the force reached 696N at 6mm, at which point no further distraction was done. The second rod was also restricted to the same amount of extension, although it did not show such a high load. As there were only six patients in the study and most of them had only one extension performed, the data cannot be statistically compared but the result shows a generalised trend and expected behavioural pattern. Generally there was a residual load on the rod that needed to be overcome before the extension could commence. The soft tissues then induced additional force by stretching.

Regression performed on pooled data has indicated an initial load of 183N which increases at a rate of 30N per millimetre with a Pearson's product moment correlation coefficient of only 0.33, indicating that the data is very scattered. There is also a threshold of about 600N and 11mm extension beyond which very little increase was allowed. The maximum 11mm extension was based on the surgeon's perception of comfortable extension.

6.5 Discussion

The main objective for this particular study was to establish a set of parameters that we can adapt in the development of a non-invasive growing rod for the treatment of juvenile and adolescent scoliosis patients. We have established that a peak load carrying capacity for a mechanised growing rod may not exceed 600N and that the rate of growth of about 30N per millimetre would suffice, giving a maximum of 20mm of growth during one session where each session should not be longer than 30 minutes.

To justify the use of these parameters we need to look at how they were achieved as there are some fundamental questions. In our study almost all of the patients had two rods, each anchored at one end at the extremities and joined in the middle with a domino as shown in Figure 6.2. Each rod was extended in turn, one after another. In theory, force exerted on one rod should be balanced by the second rod and therefore once the first rod is extended creating a force, the second rod should continue from the load created by the previous rod increasing even further when extended. In fact this was not evident in our experimental result shown in Table 6.2. So, how did the load disappear as soon as the domino was locked after the first rod extension? In fact the domino is not anchored to the bone and therefore it cannot offload any force onto the spine. The only plausible explanation is that the load is purely created by the way the patient is laying on the table under full anaesthesia. Small displacement in the position can either increase or decrease the resistance to the extension. With that argument in mind, for a non-invasive device where the patient is expected to be fully conscious and able to move around, he/she can easily take up a posture that reduces the load on the implant whist the rod is being extended. Stokes *et al.* (2004) has described theoretically that the spinal force is greatly affected by different muscle activation strategies and that these strategies may determine whether or not spinal loading causes scoliosis progression during growth. The most important factor in his study is that the force is significantly affected by muscle activations and it may be that the implant load can be reduced by activating different muscle groups. This is exactly what we need

to achieve to reduce implant load. If this is true, then a smaller load carrying capacity would be adequate, provided that the device when not activated is still strong enough to support the cyclic loading exerted during normal activities.

There have been several studies in the past to measure distraction loads applied during surgery (Waugh, 1966; Elfstrom *et al.*, 1973; Dunn *et al.*, 1982). Dunn *et al.* (1982) have produced comprehensive measurement data showing a maximum load of 981N (100 kgf) with an average of 706N (72 kgf) measured by two surgeons. Waugh (1966) has recommended a maximum force of 294N (30 kgf) which is half the average fracture load he measured to ensure that when a hook device is used, no fracture occurs to the thoracic lamina. Therefore, it is important not to exceed a 600N load which is well correlated with our maximum load recommendation. The amount of growth can only be determined by the comfort factor of the patient and how much external manipulation is applied to reduce the load. No one knows or can speculate about these factors until a clinical trial using the new device has taken place. It is assumed that the measurements obtained under surgical conditions will probably not apply for a device that can be extended almost anywhere under different set of circumstances. Also, being considerably less traumatic, the extension procedure could be as frequent as required, allowing smaller more controlled growth and plenty of time for the body tissues to react and adapt to new conditions. In conclusion, the aim of the new device should be to try to achieve the specified capacity listed above with a manageable compact device suitable in size for very young children.

Infection and instrument failure are the two major complications currently faced by surgeons. With a reduced number of surgical interventions, the new device will surely address surgery related infection. However, implant failure may still occur, as it is the implant attachment that usually fails first. The actual fracture of the rod itself is not reported, presumably because rods do not fail, before the fixation.

The new concept:

Transferring this experimental data to the development of a device for a non-invasive distraction will take into account these factors:

- Adequate strength when not activated to ensure there are no implant fractures.
- 600N load capacity when being extended and the ability to extend with any load up to the peak load.
- Extend at a rate of growth of 1mm per minute.
- Allow use of at least one of the currently available spinal systems.
- Allow rods to be bent to match the sagittal natural spinal curve.
- Up to 100mm of growth.
- Be compact in size to fit the smallest of patients.
- Powered using inductive coupling, for the reasons given in the next Chapter, to drive a motor.
- Have a feedback to allow accurate determination of the growth.
- Optimise the design based on frequent smaller increments with adequate recovery time in between the extensions, providing a much better controlled and comfortable extension for the patient.
- Determine the practical limitations of the new device and complications associated with patient treatment and daily activities of the patient.

The result presented in this chapter satisfies the project aim listed in paragraph 1.6, (B), (a) [Chapter 1, page 49].

CHAPTER 7

DESIGN AND TESTING SPINAL IMPLANT

7.1 Introduction

The distractive force associated with a spinal rod during surgical lengthening procedures in scoliosis patients was established by clinical measurements taken in a small number of patients as described in Chapter 6. In this study, due to the limited number of patients, there was no distinction made between thoracic and lumber deformity, but one would estimate that the lumber region would require a larger force to straighten the spine simply by its rigidity in the coronal plane. Also, it was speculated in the same Chapter that the distraction force may in part be related to the patient's posture, i.e. the way the patient is laying on the operating table at the time of the lengthening procedure. It may be possible to reduce the load by adjusting the patient's position in a non-invasive lengthening with the patient fully awake. We needed to design a device that is small enough to fit a small patient but is strong in construction to support loads generated during daily activities.

The degree of deformity, measured by the Cobb angle, is shown in Figure 7.1. The Cobb angle, together with the arc length and the distance between the fixation points, dictates the amount of extension that is required in an extending rod. From the literature (Patwardhan *et al.*, 1990) it was estimated that where there are double curves, the extent of the deformity might extend between T5 and L4 with the shortest curve being in the lumber region between T11 and L4. From this, approximately 100mm of growth is estimated for a motorised spinal implant. From a surgical point of view the approach can either be anterior or posterior. An anterior approach is more risky and is usually for small scale treatment with a small device using endoscopy type equipment. For rod-type implants a posterior approach is more suitable. With a posterior approach the only place where an implant can be attached to a vertebra is between the Spinous and Transverse processes in the pedicle of a vertebral arch, using screws or using a hook device that is wedged in at the lamina or onto the transverse process (Figure 7.2). The central part of the rod where the domino is attached is placed sandwiched in between Latissimus dorsi/Thoracolumber fascia and Spinalis.

So, when the rod is extended the mid section effectively traverses in between the muscles towards the spinal process, pushing the spine straight.

Spinal implants are widely available commercially and the fixation techniques are now well established. Historically, 5 to 7mm rods are used which provide sufficient strength whilst allowing surgeons to set or bend them in the sagittal plane to match the natural profile of the spine.

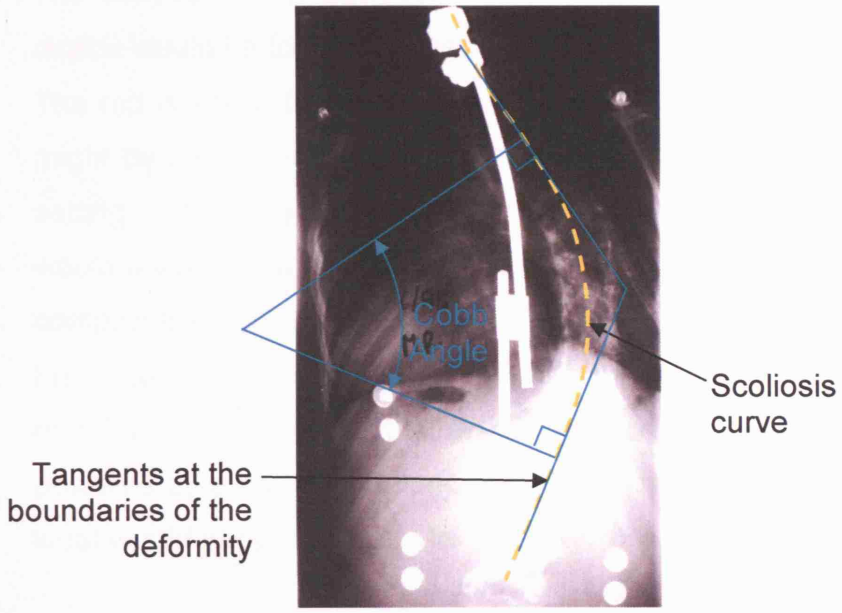


Figure 7.1 Cobb angle measured between tangents produced at the extremities of the scoliotic curve.

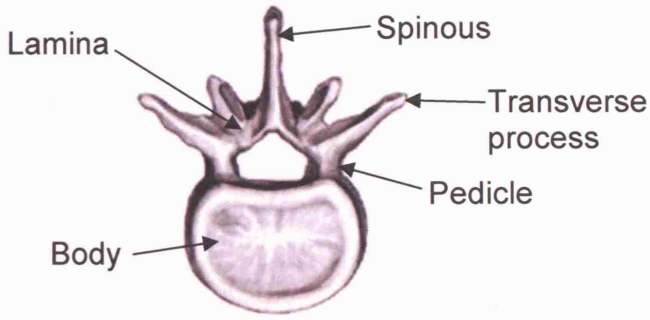


Figure 7.2 Anatomy of the vertebra.

A motor driven device was produced by Takaso *et al.* (1989) that was tested in a canine model which showed a very good result, however, there are some critical issues with this design.

- Although, the authors suggest that the load generated was comparable with that measured by Moe in the Harrington rods, it is only one third of the value we have measured in our study, indicating there is a need for a more powerfully device.
- The construction is such that in order to provide 100mm of growth the device would be too long to be used in young patients.
- The rod is screw threaded and is being rotated inside the tissues, which might be detrimental and problematic. Also, in children the rod will need setting in the sagittal plane to match the natural spinal curve and this would prevent rotation. It would also require universal joints at both ends, complicating the design.
- From our experience we found that this treatment can last for 18 to 24 months in the patient. This device has electronics and an electric motor powered by a battery. It is not clear how long the battery would last and what would happen if the battery were to be completely drained.

The objectives for my design are to:

(a) Develop a gear mechanism to extrude a 6mm diameter rod driven by a gearbox and a miniaturised electric motor giving a load capacity close to 600N with a device small enough to fit into a juvenile.

(b) Expand the electro-magnetic concept developed for bone tumour patients specific for scoliosis treatment, eliminating the need for an internal power source.

7.2 Design evolution

From the onset it was intended to utilise, wherever possible, commercially available components. There are a number of spinal systems utilising 6mm diameter rods and therefore the device must accommodate this spinal instrumentation. There are also a number of commercially available miniaturised electric motors that are suitable for our system. Therefore, we need to evaluate the rod size, primary drive unit, the secondary drive unit, the power requirements and feedback system.

The power supply and a telemetry system to monitor speed are currently being developed under a separate study. However, the principal technologies involved are:

Induction coupling:

This is a well established technique where inductive coupling is achieved by two electrical coils:

a) The implant coil is positioned subcutaneously, remote from the implant site, and is joined via a flexible umbilical cable. The AC voltage generated by the coil is converted to a stabilised 12V DC power supply by the onboard electronics before feeding to the motor. A schematic is shown in Figure 7.3.

b) The external coil, which is a hand held device, is placed over the implant coil to produce an inductive coupling, thus generating electrical power in the implant coil.

Speed monitoring:

Donaldson (1986) described the use of passive signalling via inductive coupling, which is the technique used in this application. The speed is monitored through the encoder output. As the gear reduction is prefixed, the

actual implant growth can be established by monitoring the motor speed. The encoder output is converted into pulses, one for each revolution of the motor, and is then used to short-circuit the implant coil thus causing a reflective pulse on the external coil. Monitoring the external coil provides a simple but effective method for counting motor revolutions. The device is capable of detecting motor direction. The same technique was previously used by Taylor *et al.* (1997) for a more complex array of force measurements in the proximal femoral replacement.

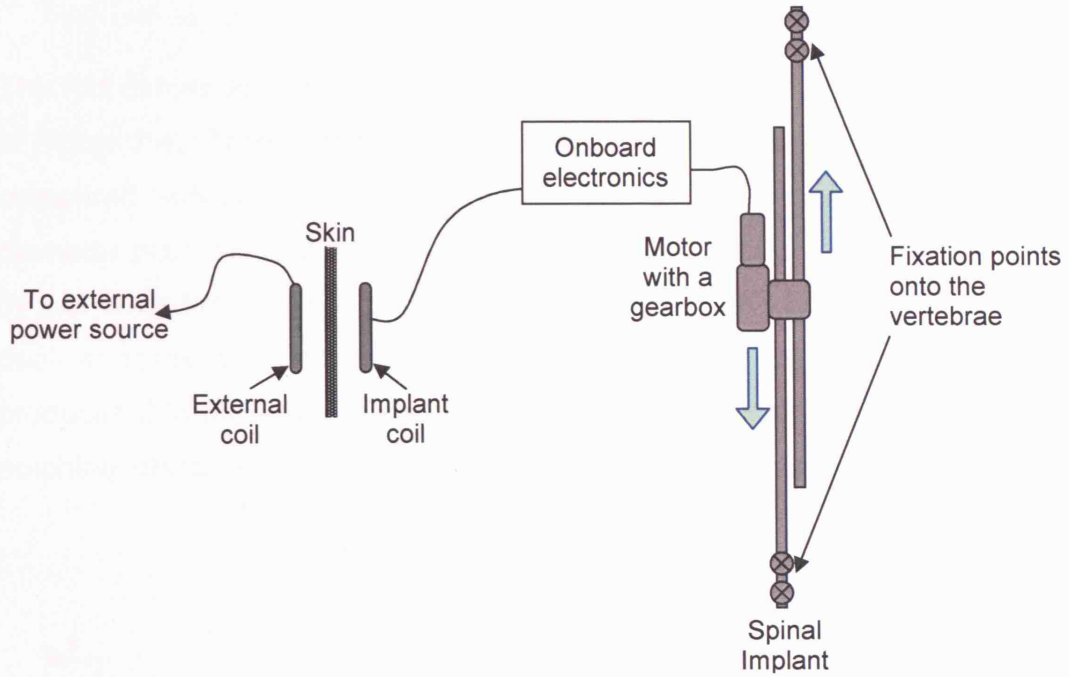


Figure 7.3 Schematic of the implant and coil arrangement.

7.2.1 Rod modification

For a spinal rod to extend, it needs to be pushed from the end or another possibility is to use a threaded rod which is extruded through a rotating nut. Both of these concepts can produce controlled growth without causing uncontrolled reversal. Pushing from the end is similar to a threaded rod as both can be driven by a screw mechanism to produce the thrust. There are other techniques to extend telescoping sections, as discussed in Chapter 3, but the mechanical screw device is considered simple and effective. The space is limited and therefore the rod needs evaluating for strength.

The rod carries an offset load creating bending and compression, as shown in Figure 7.4. Threading the rod reduces strength by an appreciable amount compared with an equivalent plain rod. For comparison, looking at a 6mm diameter plain rod, the analysis showed that for an axial load of 600N offset by just 5mm from the centreline, 120 MPa tensile and 163 MPa compressive peak stresses are produced. The same conditions applied to a M6 screw produces 275 MPa tensile and 338 MPa compressive stresses because of a notching effect and reduced sectional area. The analysis was performed

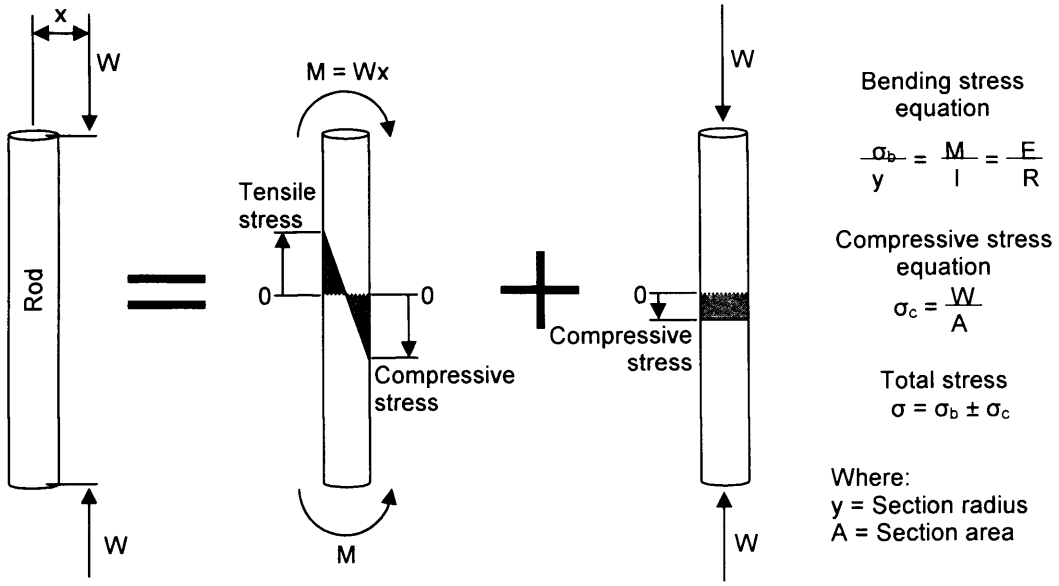


Figure 7.4 Stresses in a rod due to offset loading.

assuming a stress concentration effect produced by a V shape, circular notch equivalent to a 1mm pitch ISO screw thread on a 6mm rod, as defined in Roark's Formulas for Stress and Strain – 6th Edition, 1989, page 738. Thus, the 6mm screw has only half the load carrying capacity compared with a 6mm plain rod. To check that this is not under estimated, a plain rod equivalent in diameter to the core diameter of a M6 screw was analysed using the same conditions which gave 225 MPa tensile and 289 MPa compressive stresses. Finite Element Analysis (FEA) can provide a much better indication of stresses, but this simple analysis gives a good estimate of how the strength is compromised by the threaded rod. To have a threaded rod that has a comparable strength to that of a 6mm rod, it needs to be M8 with 1mm pitch. For the spinal application, a rod of 8mm diameter is too large and therefore unacceptable. In order to maintain a small size and be compatible with other instrumentation, there is no choice but to accept the rod with M6 threads.

The material used for the spinal system is usually stainless steel or titanium alloy and it is the manufacturer's prerogative not to divulge material specifications, but one can assume mid-range properties were used. Therefore, it is recommended that hard grade wrought nitrogen strengthened stainless steel, ASTM - F1586-02, Grade hard, be used for the screw to provide additional strength. A screw made from this material can sustain a maximum bending moment of approximately 10 Nm.

The material used for the prototype is EN40B, which has a proof stress of 710MPa. This material provides a safety factor of 1.2 for an offset load of 600N at 10mm (= 6Nm bending moment) and 1.5 for an offset load of 500N at 10mm.

7.2.2 Primary drive unit

As explained previously, this concept was generated around a commercially available primary drive unit. A small DC motor with a gear-head and an encoder to monitor the speed with reasonable torque output was available from Faulhaber GmbH & Co, Germany. Figure 7.5 shows a typical 12mm diameter motor. This unit, inclusive of encoder, is 64mm in length generating a maximum 0.3 Nm torque and maximum output speed of 12 rpm from a 12V DC power supply. The unit is constructed from stainless steel and plastic with cables for power input and encoder output. The unit requires encapsulation and cable connection to the coil.

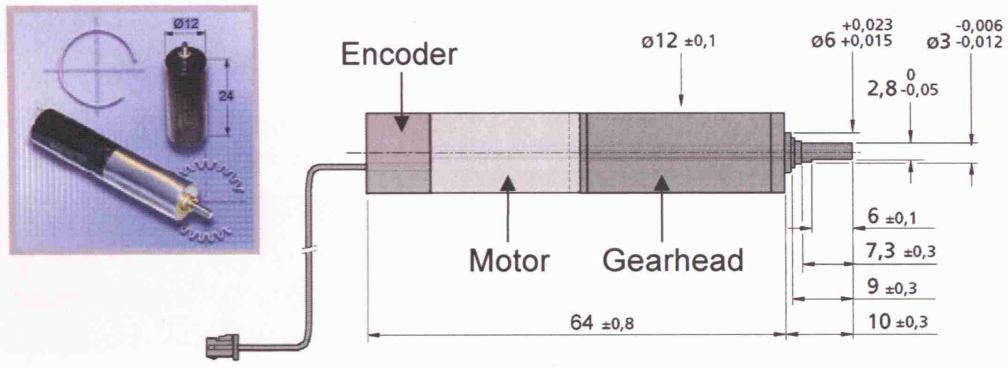


Figure 7.5 Primary drive unit from Faulhaber GmbH & Co, Germany.

7.2.3 Secondary gearbox unit

As described previously, the output from the primary drive unit was 0.3Nm at a maximum speed of 12 rpm. To connect this drive to the rods several gear systems were evaluated.

Worm drive:

Initially it was thought that the only place where the motor could be positioned was parallel and alongside the rods, interconnected with longitudinal and transverse worm drives as shown in Figure 7.6. In this design both rods have screw threads in order to push them in opposite directions by two separate drive gears rotating in opposite directions, thus expanding the spine. Drive gears from each rod are driven by a single cross worm with right and left hand teeth. This cross worm itself is driven by a second worm/wheel directly connected to the primary drive unit. The pitch between the rods was maintained at 10mm as it is in conventional rod systems.

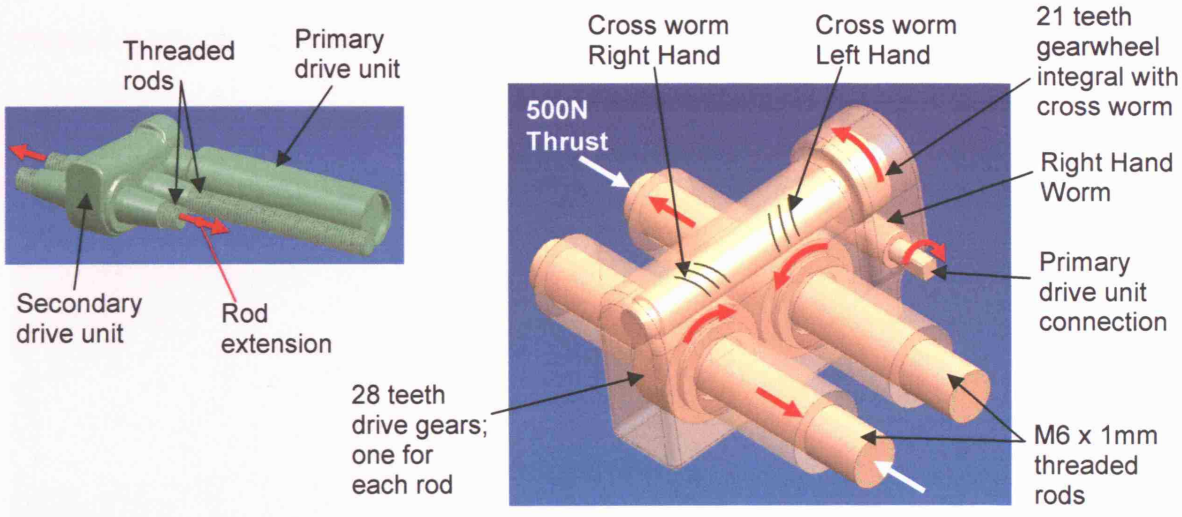


Figure 7.6 Worm drive with relative motions.

The only drawback with this system is that any imbalance in resistance between the drive gears is likely to cause the gearbox to spin around the rod with least resistance. One further consideration is that worm drives are not very efficient due to sliding motions between the teeth, so having two in series makes this device inefficient. To overcome spinning and to increase the efficiency, a single rod system could be used.

The speed ratio with this arrangement cannot be much less than 504:1 and to provide about 1mm growth per minute, the primary drive unit needs about 500 rpm output. This is possible using a low ratio primary drive, but the speed becomes much more sensitive to the output torque and the heat dissipation becomes an issue. Also, calculations showed that the input torque required to lift a 600N load is about 0.57Nm which is more than the primary drive unit can cope with. For these reasons, it was concluded that this concept could not deliver the required load carrying capacity.

Spur drive:

An alternative design utilising a two rod system was also evaluated for size. In this design the primary drive was placed over the rods and although created a much narrower device, it was too high (Figure 7.7) to fit in the

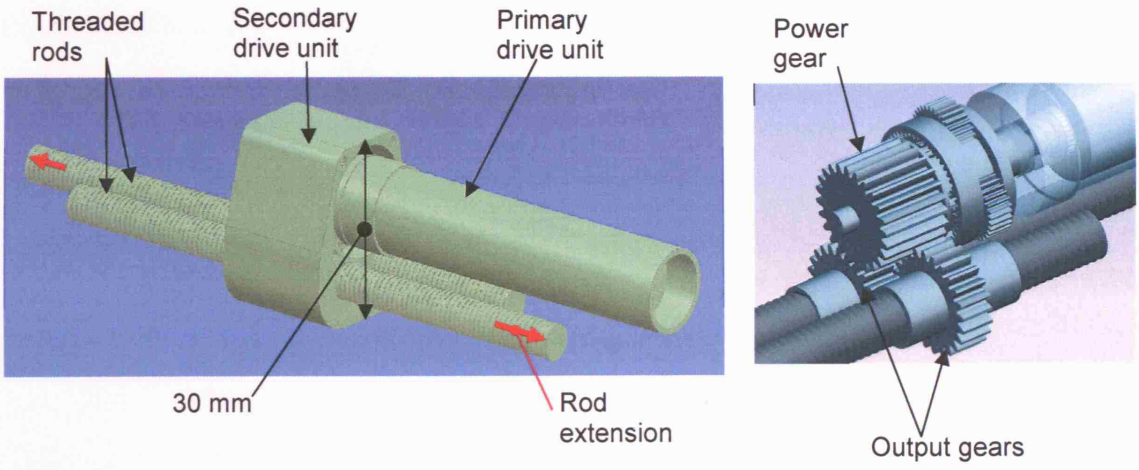


Figure 7.7 Spur gearbox with primary drive positioned above the rods.

patient. The problem with spinning as a result of imbalance in output gears still remains. This is a typical problem with a two rod system. The only way to overcome this is to link the output gears and the power gear together forming a triangular configuration. However, this is not practical as the accuracy required in machining and assembly would become very difficult to achieve.

In order to reduce the overall size, a single rod system was then considered. In this design the main body of the device is attached rigidly at one point of the spine, whilst the threaded rod is attached at the other point on the spine. With this device the torque generated in the screw to push it forward requires resistance by the spinal fixation points at both ends. Therefore, the torque required to push the rod forward using a gearwheel requires quantification to ensure no overload is created on the fixation points. This basic design shown in Figure 7.8 consists of a screw with a drive gear resting on a support. The torque equation used in Chapter 3, Section 3.2.3, Equation 3.10 applies to this application in a similar way.

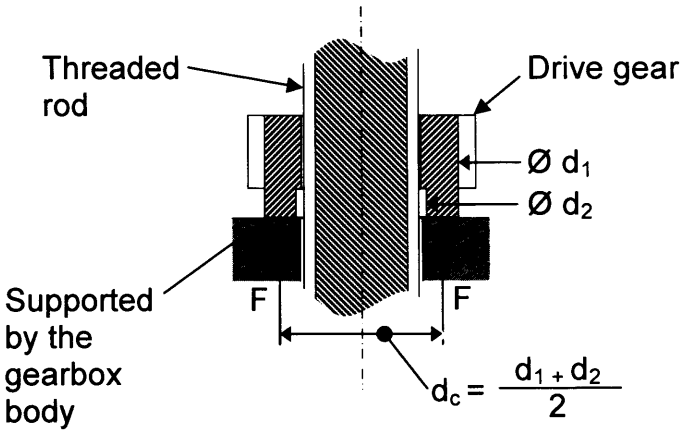


Figure 7.8 Drive gear with threaded rod and supports below.

$$T_s = \frac{F\, d_m}{2}\left(\frac{l + \pi\, \mu\, d_m\, \mathrm{Sec}\, \alpha}{\pi\, d_m - \mu\, l\, \mathrm{Sec}\, \alpha}\right) + \frac{F\, \mu_c\, d_c}{2}$$ From Equation (3.10)

Where;

F	= Total load carried by the screw	= 600 N
d_m	= Pitch circle diameter of the screw thread	= 5.3 mm
l	= Thread pitch	= 1.0 mm
μ	= Coefficient of friction at the screw threads	= 0.45
μ_c	= Coefficient of friction on the end thrust	= 0.45
d_c	= Mean diameter of the drive gear taking load	= 8.5 mm
π	= Pie	= π
α	= Half angle of screw thread	= 30°

Therefore,

Torque on gear wheel	T_w	= 2.1 Nm
Torque on rod	T_r	= 1.0 Nm

The torque transmitted onto the spinal fixation is about 1Nm at both ends. Fricka *et al.* (2002) have conducted a detailed experimental analysis of bovine spine with a single and dual rod system and have measured applied bending and torsion stiffness under a cyclic loading condition. They demonstrated that by applying ±2 Nm torsion with 5N axial load, the presence of instrumentation significantly affects the overall stiffness indicating that the instrumentation is subjected to daily torsional moment. They also showed that the intact spine had higher stiffness than the single rod, indicating that surgery greatly reduces spinal stiffness. Although the actual values cannot directly be applied to the human spine, it suggests that there is significant torsional resistance imposed by the spinal instruments in the body and 1Nm torque created by the motor in our design is probably insignificant in comparison.

As the primary drive has a torque capacity of 0.3 Nm and 12 rpm maximum speed, the secondary gearbox needs only x10 torque amplification and a speed ratio of about 12:1 to provide a growth rate of 1mm per minute.

Based on these conditions, a final system with a single rod with motorised drive is shown in Figure 7.9. In this system the secondary gearbox unit provides 12:1 reduction and it is expected to have over 90% efficiency. A prototype device is being constructed and is to be validated shortly. The design incorporates a pair of seals on the output gear to prevent body fluid and lubricant reaching the opposite side. There is also a smaller seal in between the primary and secondary units preventing cross lubrication.

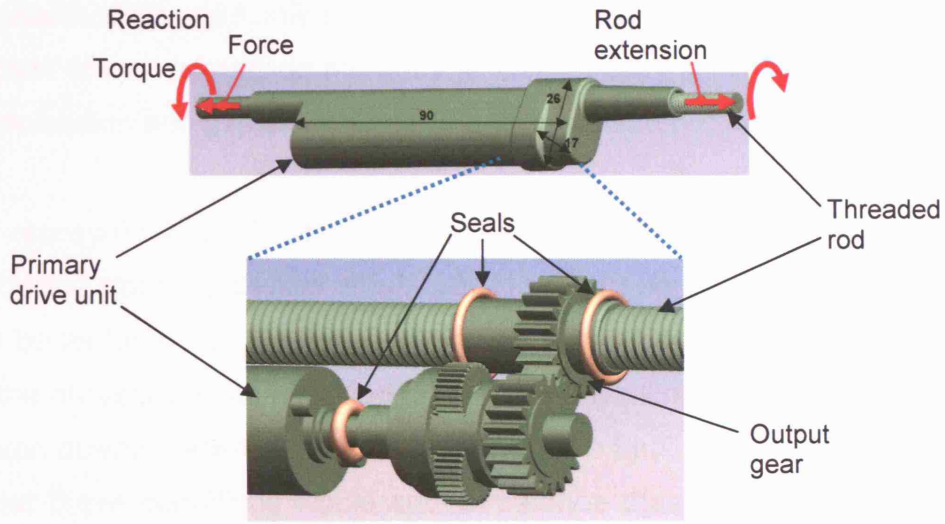


Figure 7.9 Single rod type with a primary drive unit coupled with secondary gearbox unit (exploded view) with seals proposed for the clinical evaluation.

This device is expected to have an overall efficiency of around 50%, which is not very good, and it is still relatively large for the youngest patient that might be treated. One possible solution to reduce the size is to make the device in two parts. The rod with a single pair of gears connected with a remote drive unit with a flexible spindle. This would allow the drive to be located in an area where more tissue cover is possible.

7.3 Testing

As discussed earlier, the spinal rods for scoliosis treatment are always placed on one side of spinous process and the natural curve in the sagittal plane is matched.

The body of the implant shown in Figure 7.9 is substantially stronger than a 6mm rod and hence there are no stress complications in the body. Therefore, during the extending procedure, the rod section inside the body and the gear mechanism are protected from bending loads. To test the gear mechanism we need only to apply compressive load. However, the threaded section of the rod outside the body is likely to experience bending as well as compression and this section needs both axial and bending loads.

To represent daily loading cycles we need to consider the anatomical modelling done by Stokes *et al.* (2004) which suggests inter-vertebral force can be as high 1.5 kN taken between six lumber segments (which is 94% of all the measurements obtained by the authors using all three strategies with eleven activity based bending conditions). An application of a distraction rod under these conditions would counterbalance these forces where the force and moment generated in the rod will depend on its position and the amount of bend introduced in the rod. Strain measurements in an instrumented spinal rod obtained by Waugh (1966) yielded 677N (69kp) when the patient vomited approximately 5 hours after the operation. After 24 hours the force was about 196N (20kp) during sitting and standing activities. The whole purpose of the spinal rod is to provide consistent support to the spine and therefore, the load carried by the rod should not be allowed to fall below a certain level in order to correct the deformity.

To ensure that the gearbox is strong enough for the application, we need to apply two load conditions: cyclic load to mimic daily activity of the patient and a distractive force exerted during the lengthening procedure. The distraction should be tested at zero up to a maximum of 600N load for 10 extension cycles, whilst the cyclic load should be applied between 200 and 500N at 1 to

2 Hz for 10 million cycles. To introduce a bending moment in the implant, as discussed above, an offset of 10mm should be applied for both loading conditions. Figure 7.10 shows test apparatus with two modes of loading

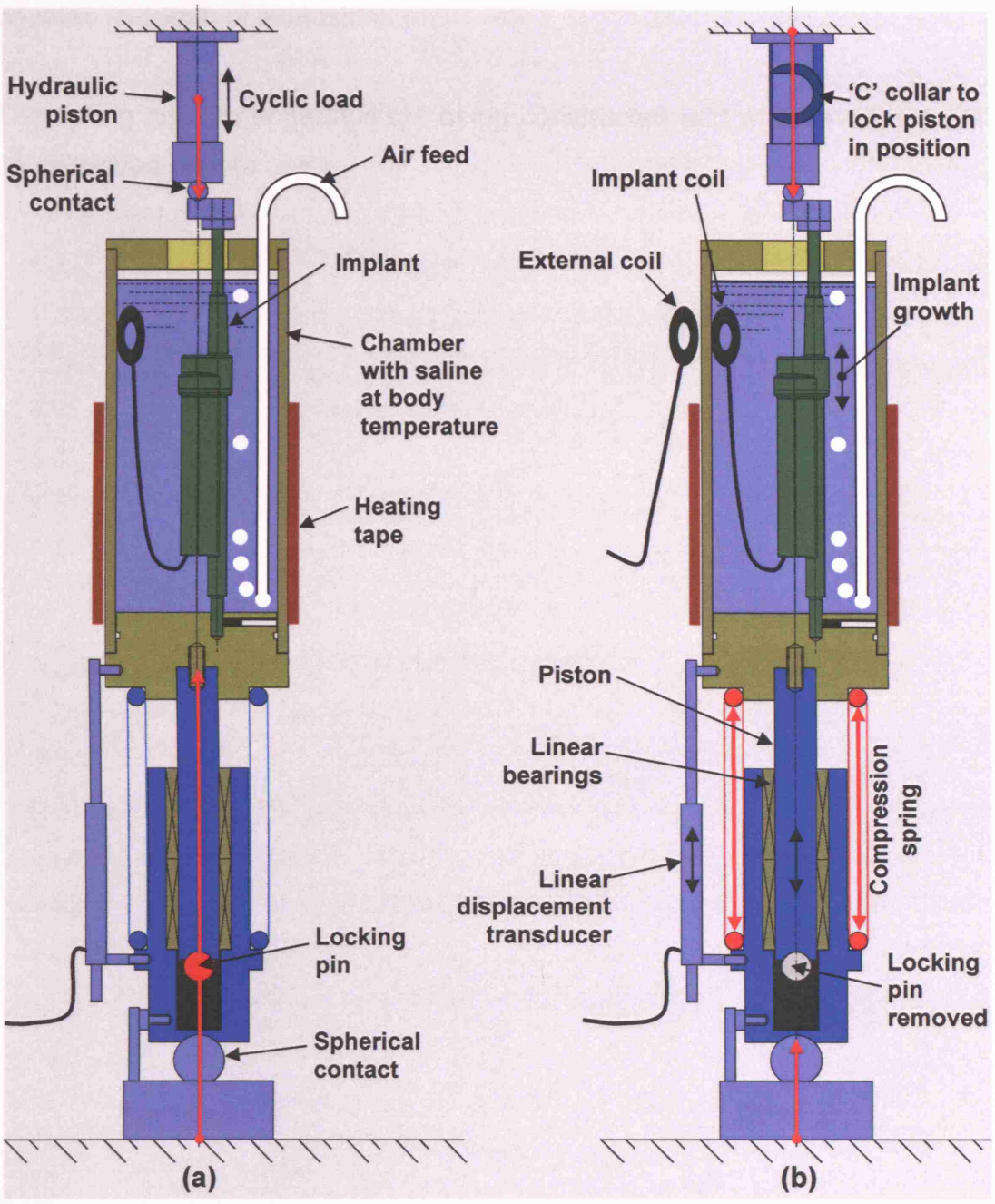


Figure 7.10 Test apparatus: (a) when cyclically loaded, (b) when implant is extended using induction coil against a compression spring. In both cases the implant experiences compression and bending loads.

conditions combined in one; cyclic loading is applied as in (a) where the test is stopped at regular intervals when the implant is distracted against a compressive spring as in (b) and is then retracted back to the original length before continuing cyclic-loading once more. The spring is designed to provide a rate of compression of 40N/mm and for a 600N peak load, this equates to 15mm of extension.

The spring and the apparatus are being constructed and when available will be calibrated prior to use.

7.4 Discussion

From the literature it is clear that some analytical and practical work has been done to evaluate spinal forces. However, the only analytical work carried out that represents daily loading is by Stokes *et al.* (2004). This evaluation was done to identify different muscle activation strategies to self correct spinal deformity. This gives some idea of how change in posture affects the level of force in the spine. The direct force measurement conducted by others and in our study is not really measured in relation to the neutrally balanced muscle forces. It is affected by the way the patient is positioned and restrained. Waugh (1966) measured force supported by the rod for a short period of time after the operation and recorded changes during coughing or vomiting. The bovine spinal work conducted by Fricka *et al.* (2002) has shown how spinal stiffness is affected by the presence of single or dual rods and that stiffness of the spine is reduced by surgery itself. There is not a clear cut indication as to how much load to apply during testing and the load estimated by clinical measurements would probably give a much more conservative assessment.

The design of a worm type secondary gearbox is demonstrated to have inappropriate speed reduction and low efficiency, and the use of a dual rod system has problems associated with the imbalanced frictional losses causing the implant to spin. Hence, both of these designs are considered inappropriate for this application. The use of a spur gear train has better efficiency, but the efficiency is lost as the gear train gets longer. The efficiency of the commercial gearbox incorporated in the motor is only about 55% because of a high reduction ratio. This can not be overcome until more powerful motors are produced with increased torque output. Therefore, the design proposed for testing is probably the most efficient that we are likely to achieve using today's technology, given the space restriction.

The weakest link in this design is the rod that is threaded to provide the propulsion. Improved material properties do provide comparable strength to that of an existing 6mm plain rod, but for the future it would be beneficial to find a propulsion solution that can be used with a plain rod.

The result presented in this chapter satisfies the project aim listed in paragraph 1.6, (B), (b) [Chapter 1, page 49].

CHAPTER 8

GENERAL DISCUSSION

8.1 General discussion

Implants used to treat bone tumours are inert and are unable to perform many of the functions of the bone they replace. For young children, the main function of the bone and growth plate that may be removed during surgery is to provide axial growth of the skeleton.

With respect to a growing prosthesis for bone tumour treatment in children, there are basically limited solutions available of which only two are truly non-invasive in nature for the post-implantation extending mechanism. The Phenix device, described in Chapter 1, with a compressed spring mounted in a resin block has several disadvantages: it is non-reversible and there is a possibility of the device being extended unintentionally. Also, the spring, as it expands, is subjected to the daily loading cycles producing pumping effects. Despite this, the device can be used in infants and perhaps this is the only device currently available that can be made small enough for very young patients. The other device developed by Verkerke *et al.* (1994), has not been successful due to fretting corrosion at the thread interface which was carrying the daily load cycles.

The device developed and reported in my thesis is not greatly different in principle to that produced by Verkerke *et al.* (1994). The main difference is that the analysis and review presented in my thesis is based on the estimation of power requirement throughout various parts of the system and making the device as efficient as possible. By doing so, we now have a baseline for future developments utilising mechanical concepts constructed from available materials. Finding better and stronger materials for the various components of the system would provide options of either reducing the size of the components, making the device much more compact, or increasing the load carrying capacity so that the device can be used in other applications. The use of better manufacturing techniques used for the manufacture of the device reported in my thesis, could further enhance the strength of the implant by allowing the manufacture of the parts from much harder and tougher materials with an adequate level of accuracy.

The concept developed by my study is clinically tested and has shown, like any new concept, a number of complications as described in Chapter 5. Some of these complications may be purely teething issues since the experience gained is relatively low. Furthermore, the device is evolving and the functional understanding is increasing with time. Despite these negative issues, general acceptance of the device has become established because of the level of its potential benefits and the improved comfort to patients. This is demonstrated by the number of implants inserted in a relatively short time. This, however, puts greater emphasis on continual monitoring and refining the device so that it continues to improve.

Often un-linked parts of the system, such as the drive unit which is not directly connected to the prosthesis, appear to be less critical. This is not the case here as this concept could not work properly without the efficient and user-friendly drive unit. Although the compactness and simplicity of the drive has been achieved there is still some further work needed to make the system self monitoring during the growth of the prosthesis so that the element of uncertainty during the lengthening procedure is removed or minimised.

I have already proved that the concept can be made smaller as in the spinal application where the forces are much reduced and that the life of the device is relatively short. Generally speaking, the limitations are in the material and manufacturing processes where the costs can become prohibitive. These complex parts are expensive to produce. However, with time enough experience will be gained and as the technology for the material and the manufacturing improves, so will this implant.

One of the features that would be an improvement/refinement to the concept is the modularity of the growth element. The current manufacturing practice is to create an implant with maximum lengthening capacity or at least enough growth for the patient to last till maturity. For those patients who do not have enough growth to last till maturity, the length of period before revision could

be several months or more commonly several years. Through the clinical use of these implants, it has become apparent that when a patient needs a revision to provide additional growth and the implant is well fixed into the bone, destruction to the fixated bone caused by removing the implant is too large. To provide additional growth after an implant is fully extended strongly suggests the necessity for modularity within the growth module. Fixation of the implant would then not be disturbed during revision surgery simply because the patient needs extra growth. Furthermore, modularity would make the prosthesis more versatile even at the initial insertion.

The minimally invasive growing prosthesis has a potential for having an uncemented fixation and hence over 30% of these patients who have been treated with this implant have had uncemented intramedullary stems. In an uncemented implant the stem is made to fit tightly into the remaining segment of the bone and therefore it requires impaction into the bone using a mallet. There is however, a surgical preference for hydroxyapatite coating on the stem and a coated stem would require greater impaction due to its rougher surface than a plain stem. The benefits of an uncemented stem are sound fixation and longevity, particularly in younger active patients. In the non-invasive prosthesis, because of the presence of a sensitive gear mechanism and a magnet, impaction of the prosthesis is under question. During impaction the blow is directed axially along the length of the prosthesis and if hit hard enough, might damage the gears or the magnet. Also, a sudden blow is liable to demagnetise the magnet. Therefore, it is considered desirable to make the growth mechanism detachable from the stem so that the stem can be fixed first without endangering the growth mechanism. This requirement emphasises the need for making the implant modular.

During the lengthening process, the part played by soft tissues is the most significant part for a successful outcome. As we all know and appreciate, as the tissues are stretched they become stiffer. This usually reflects in reduction of range of motion of the adjacent joint provided that they were tight to start with. Slack tissues resist less and therefore the growing mechanism

in the prosthesis does not have to do much work. The ideal situation is where there is a full range of motion with adequate tissue strength which provides a good balance between the limb function and the work done by the growing prosthesis. Clinical experience has so far shown that for tight tissues around the knee joint, a 4mm extension resulted in about 5 to 10 degrees of reduction in ROM. It is therefore important to regain the ROM at least to the pre-extension level before further extension is planned. In most patients this recovery is achieved through normal activities and there are no significant problems. Those patients who are unable to recover must be systematically treated by a physiotherapy regime to achieve a good range of motion in between the extension sessions.

A biological growth mechanism, such as distraction osteogenesis, might provide a better solution for children but there are practical issues. Baumgart *et al.* (2005), described a new concept combining an endo-prosthesis with a fully implantable motorized distraction nail that can be activated in gradual steps to lengthen the remaining bone by callus distraction in children. This is a gap filling process in combination with a prosthesis to maximise bone/implant ratio where the distraction is done in a short space of time. Kapukaya *et al.* (2000), and Erler *et al.* (2005), have also performed a number of distraction procedures using external fixators. Distraction osteogenesis requires a constant gap between two fragments of the bone where bone ossification occurs at a rate of about 1mm per week. Williams *et al.* (2005), and Li *et al.* (1999), have tested 0.2mm/day rates, which is about 1mm per week, showing good biological responce. United States growth charts published by the National Centre for Health Statistics in collaboration with the National Centre for Chronic Disease Prevention and Health Promotion in 2000, suggest an overall stature growth rate of only 1.3mm per week which is relatively constant throughout growth period of 2 to 18 years. Contribution to this growth from individual bones is a small fraction of a millimetre per week. At a slower rate of growth, it is likely to cause bone unification as the mineralization rate would probably exceed the natural growth rate of the bone. The first question is, how do we prevent bone union and continue distraction at the natural growth rate of the bone. The second

most important consideration one needs to address is how to maintain a constant gap between two fragments of the bone with an implant that migrates relative to one of the fragments, whilst allowing load transfer between the fragments. This is an engineering challenge worthy of further consideration.

8.2 Conclusion

In conclusion I have investigated the concept of non-invasively growing prostheses constructed with today's technology, and have made it a commercially acceptable item that is suitable for selected patients requiring bone tumour and spinal implants. The step-by-step analytical and experimental methodology described in this thesis, provides a foundation for all future developments. It is hoped that the next generation of devices will incorporate better materials with intelligence to control the growth of the device.

8.3 Future work

- Develop a technique based on the bone transportation concept where bone is lengthened by osteotomy and regeneration allowing new bone creation by extrusion. An application for this would be in infants with bone tumour where, after resection of the diseased bone, the space created is too small for a conventional growing prosthesis.

- For any reason, if the use of this implant is continued for adults to restore limb length discrepancy in a relatively short time, establish a maximum safe rate of expansion in combination with the range of motion based on clinical and laboratory trials. Thus define a growth chart in association with range of motion and a physiotherapy regime.

- Develop a modular growth element with attachment mechanisms at both ends to make it available in modules for 30 to 100mm growth in multiples of 10mm for inter-operative selection, revision and cement-less applications.

- Investigate reduction in gearbox size by utilising stronger materials with yield strength well in excess of 1000 MPa. Also consider placing the gearbox remote from the prosthesis to maximise growth potential.

- Develop a closed loop Intelligent Growth Monitoring (IGM) system for the drive unit utilising acoustic monitoring and software control.

- Out of a group of 27 implants, one implant failed to extend whilst 5 hesitated to extend at some stage. This is a complication rate of about 22%, which in terms of conventional surgical management of tumours using an implant is relatively high. It is clear that there is some scope to improve the magnetic coupling by increasing coil power, but there is an even greater need to improve the reliability of the gearbox. This is important as these implants are made for children who are keen to be as

normal as possible, both in accepting the implant and in their activities. Without doubt this work needs to continue for the foreseeable future.

- The weakest link in spinal implant design is the rod that is threaded to provide the growth. Improved material properties do provide comparable strength to that of an existing 6mm plain rod, but for the future it would be beneficial to find a propulsion solution that can be used without having to thread the rod.

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APPENDIX A

EXPLANTED DEVICE EVALUATION

A.1 Introduction

There are a number of different reasons that necessitates removal of an implant. These are:

- Cancer patients that are treated with limb salvage surgery are generally in remission from the disease. Chemo and radiotherapy regimes are usually continued post-surgery until the disease is eradicated. However, recurrence is common amongst these patients and the prognosis is greatly reduced. Incidence of recurrence in limb salvage surgery was compared with amputees by Stojadinovic *et al.*, (2001) who have shown that limb salvage surgery is as effective as amputation in managing the tumour, but not in improving the survivorship. Mortality is high and the cumulative survival at 10 years is only 46% as reported by Tillman *et al.*, (1997). However in some cases, if the recurrence is localised, the prosthesis is removed and replaced with a longer device. If the disease has spread elsewhere in the body then the patient is unlikely to survive for any length of time. If a patient dies the implant may be removed, but this is extremely rare. Although, 2 patients in our group died, the implants were not retrieved. However, 1 patient had localised recurrence and the limb was amputated and the implant was returned for evaluation. This is discussed below as Case 1.

- Implant may outgrow the patient in which case it requires a replacement. In this group, 1 patient had a longer revision implant. This is discussed below as Case 2.

- Infection can set in and around an implant and if this cannot be cleared with antibiotics the implant is usually removed. Lee *et al.*, (2002) reported 18 out of 145 cases requiring surgical management. In general, this requires a two stage procedure where the implant is removed and the surrounding tissues are debribed. A temporary implant or nail with bone cement containing Gentamicin antibiotics is inserted. This temporary

implant is left in place until the infection is completely cleared and only then a revision implant is inserted. Fortunately, in this group of patients there were no such cases.

- Aseptic loosening is often the main problem as discussed in Chapter 1 and in those cases the implant requires replacement. Again, in this group of patients there were no such cases.

- Implant failure can occur in some cases and this implant with novel mechanism had some technical hitches as described in Chapter 5. Since the clinical review, 1 implant was removed due to sudden stoppage of the growth mechanism. This is discussed below as Case 3.

A.2 Review of the explanted implants

Case 1:

A 10 year old male with a right total femoral replacement inserted in June 2004 to treat osteosarcoma. The implant had a "SMILES" rotating hinge knee and a large femoral hemi-head (Figure A1). The implant was custom manufactured by Stanmore Implants Worldwide Limited, Stanmore, UK. Unfortunately, after just one year, due to recurrence, the limb was amputated in June 2005. The implant was not extended in the patient and a test showed the implant to be in good working order and there were no mechanical complications.

Figure A1 Case 1: Pre-op x-ray showing diseased bone on the left and explanted implant on the right.

Case 2:

An 18 year old patient who had foreshortening in the left leg due to a previously failed implant. The patient was treated in August 2003 with a non-invasive distal femoral replacement with 60mm of growth and a fixed hinge "SMILES" knee (Figure A2) with the intention to restore the limb length in a short space of time. This was fully extended and replaced with a longer but identical implant in May 2004. Whilst in the patient, this implant was extended 16 times to 64mm in just 74 days as shown in Table 5.1, Chapter 5. During one lengthening session, the magnet stopped spinning but restarted without further complications. Throughout the lengthening period, this patient had a number of soft tissue related/stretching feelings but these were thought to be the result of rapid extension.

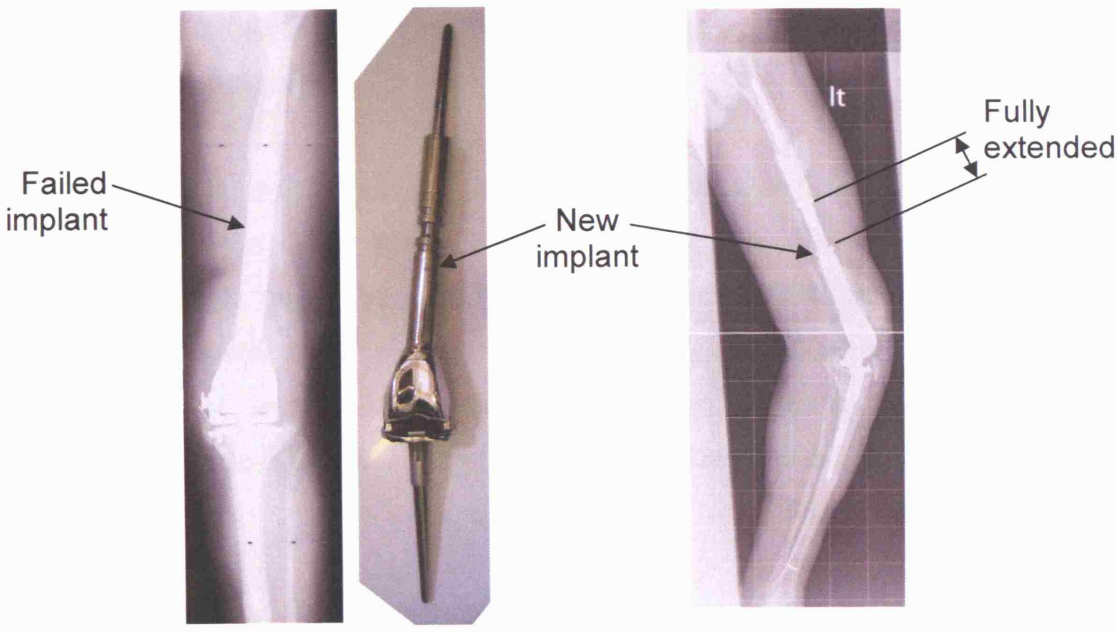


Figure A2 Case 2: Pre-op x-ray on the left showing failed implant with the explanted implant on the centre. The x-ray on the right shows the prosthesis fully extended before removal.

The explanted implant was tested in the laboratory to assess the extent of load carrying capacity after successful use in the patient. The fixture and the coil are shown in Figure A3. Here the implant was extended against a compression spring creating a gradual increase in the load. Time *v* load graph is shown in Figure A4.

Initially, it was not clear how much force the implant would generate, hence a low capacity spring was used. As shown in Figure A4, the implant easily overcame the spring force and managed to raise the load to over 2000N, at which point the magnet stopped spinning. The drive unit was then reversed and the implant load was removed without any hesitation. This clearly shows the extent of magnet coupling with the external drive unit. To assess the gearbox condition after this initial test, the implant was dismantled and the parts examined. Figure A5 shows the condition of the gear components. At this high load there appears to be minor deformation in the teeth profile and there is some wear of the tungsten carbide coating on the high speed gears. However, the gearbox is still in a usable condition. Generally speaking, the gearbox has exceeded the design criteria and the external drive coupling with the magnet is optimised.

Just to test the repeatability of this gearbox, it was reassembled and tested again against a stronger spring and this time, due to previous damage/wear, the implant only managed to achieve just under 1200N thrust (Figure A6). Even after repeated loading the implant produced 1200N which is close to the 1350N that we set out to achieve. Therefore, this experiment has clearly demonstrated the reliability of the gearbox and the power generation capacity of the implant.

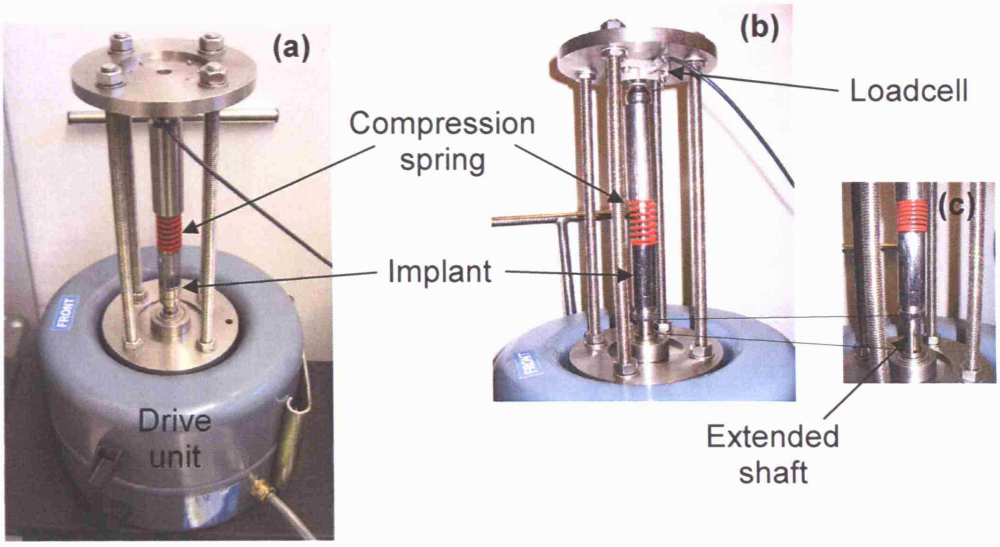


Figure A3 Case 2:
(a) The explanted implant mounted vertically in a fixture with the knee joint (where the magnet is located) inside the drive unit.
(b) Compression spring with the shaft extended to remove slack.
(c) Compression spring fully closed when the magnet stopped spinning.

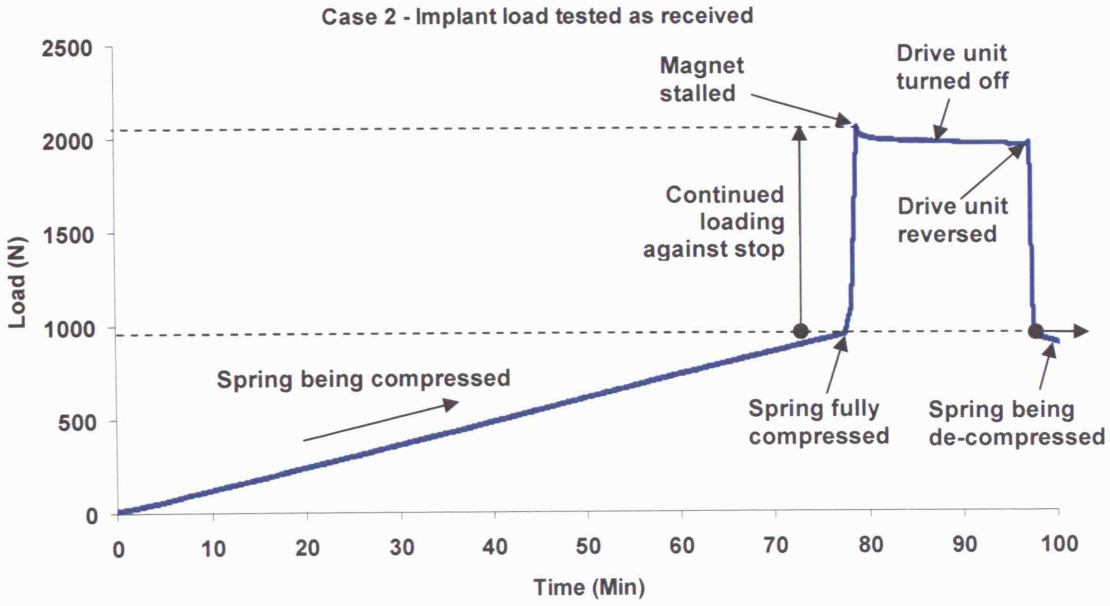


Figure A4 Case 2: Load generated by the implant gearbox when tested in as explanted condition.

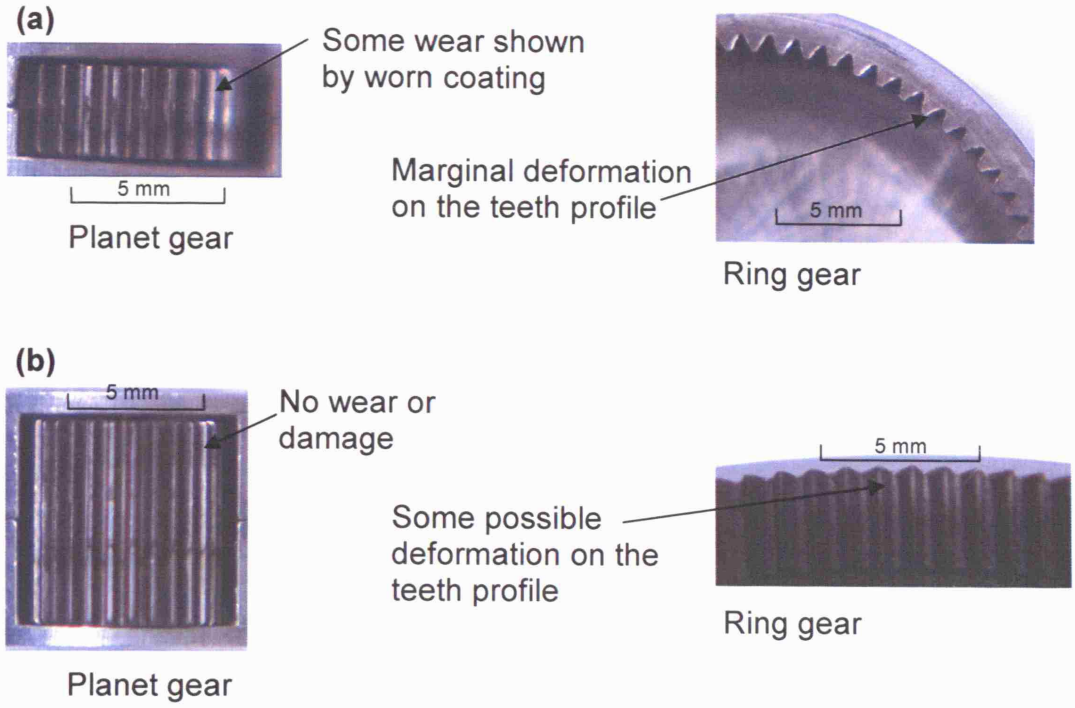


Figure A5 Case 2: Condition of gear teeth after initial test.
(a) First stage gears (High speed, low torque).
(b) Second stage gears (Low speed, high torque).

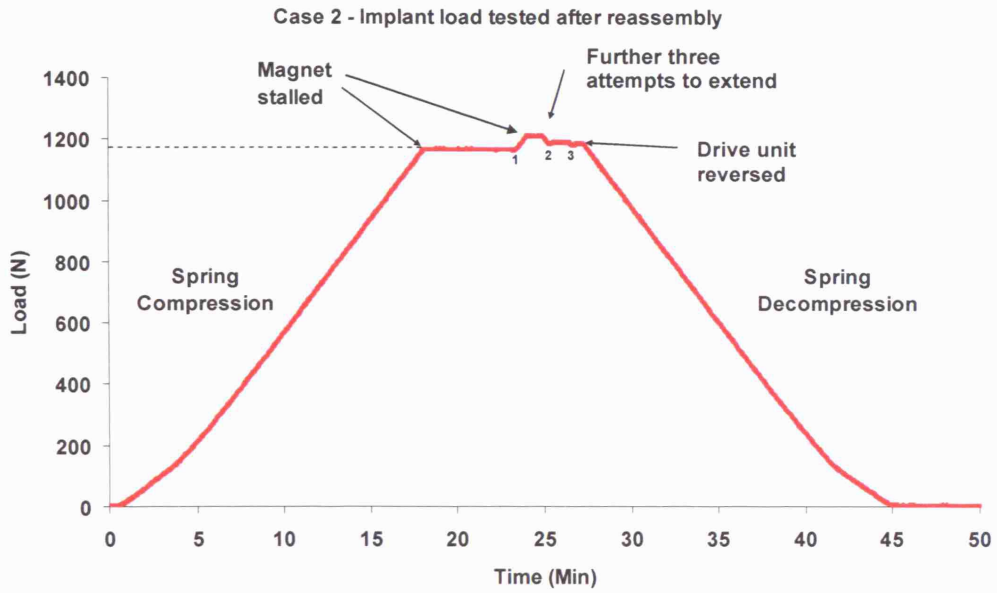


Figure A6 Case 2: Load generated by the implant gearbox after internal examination and reassembly.

Case 3:

Another 11 year old male with a right total femoral replacement inserted in January 2004 to treat osteosarcoma. The implant had a "SMILES" rotating hinge knee and a large femoral hemi-head (Figure A7). The treatment record is shown in Table A1. The cumulative extension during the first 6 extensions indicated 35.5mm of lengthening which when examined on a radiograph was only 31mm. It must be emphasised that the measurement accuracy of the radiographs is about 1mm. During this period, there were no reported hesitations in the magnet rotation. Therefore, the only plausible explanation in the discrepancy is that due to lengthy extension sessions an error in the record of lapsed time was made. Subsequently a further two 10mm extensions were carried out, but the follow-up radiograph showed only 40.6mm cumulative extension indicating that one of the extension sessions was not successful. Several attempts were made to extend the implant but the magnet failed to respond long enough, as indicated by another radiograph which measured 41.2mm extension. At this point it was decided to revise the implant and examine it.

Date	Treatment record
08.01.04	Implant inserted
29.04.04	Extended by 10 mm
23.06.04	Extended by 7.5mm
14.07.04	Extended by 6mm
28.07.04	Extended by 6mm
25.08.04	Extended by 6mm
08.12.04	Radiograph taken showing 31mm extension
17.02.05	Extended by 10mm
30.03.05	Extended by 10mm
25.05.05	Radiograph taken showing 40.6mm extension
28.09.05	Radiograph taken showing 41.2mm extension
09.03.06	Implant revised

Table A1 Extension record for Case 3.

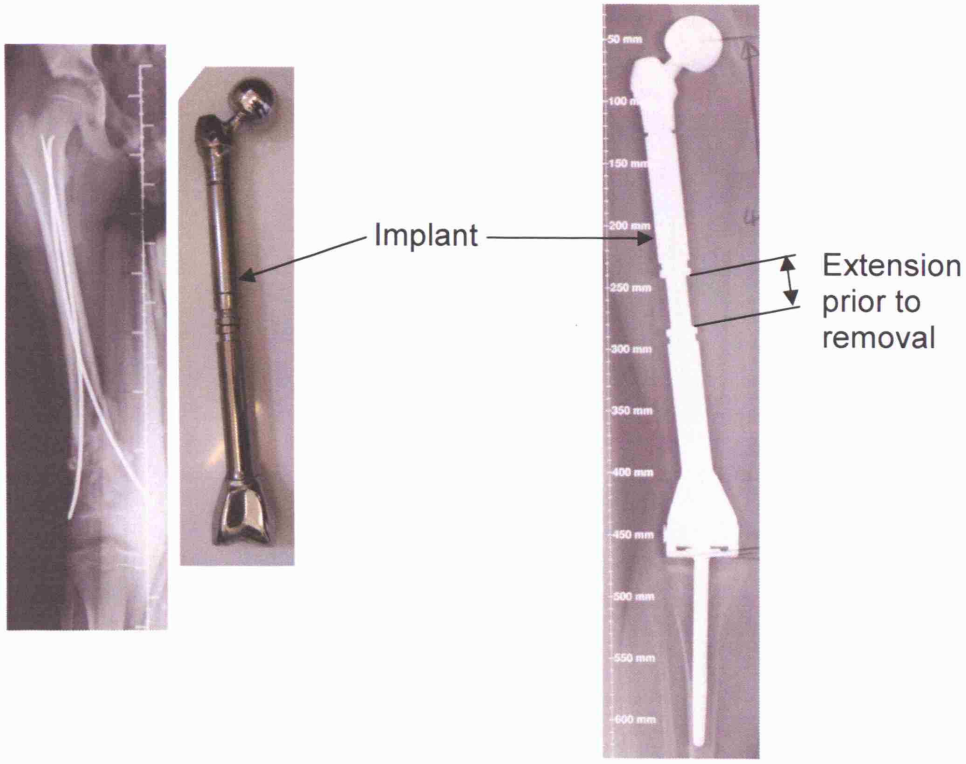


Figure A7 Case 3: Pre-op x-ray on the left showing pathological fracture with the explanted implant on the centre (picture taken after examination). The x-ray on the right shows the amount of extension before removal.

On receipt, the implant was examined visually for any external damage and there was none. The implant was then placed in the drive unit and it failed to respond. It was then discovered that the spigot was tight and that it had to be loosened with a sharp blow. As the telescoping spigot was withdrawn, the gearbox was tested again and this time it worked as normal with no hesitation. Several attempts were made to reproduce stoppage, but the gearbox worked quite well. This indicated that the gearbox and the drive were working adequately but something else was preventing their function. It was then noted that the screw inside the spigot was very tight and required considerable force to turn. As the screw was removed it was noted that there was a semi hardened fibrin glue like (creamy coloured) deposit on the screw as shown in Figure A8 (a). Further examination of the whole prosthesis showed similar deposits on the outside of the prosthesis well away from the drive mechanism. This is shown in Figure A8 (b) and (c). Probing with a sharp implement lifted the deposit up but it was relatively tough to break.

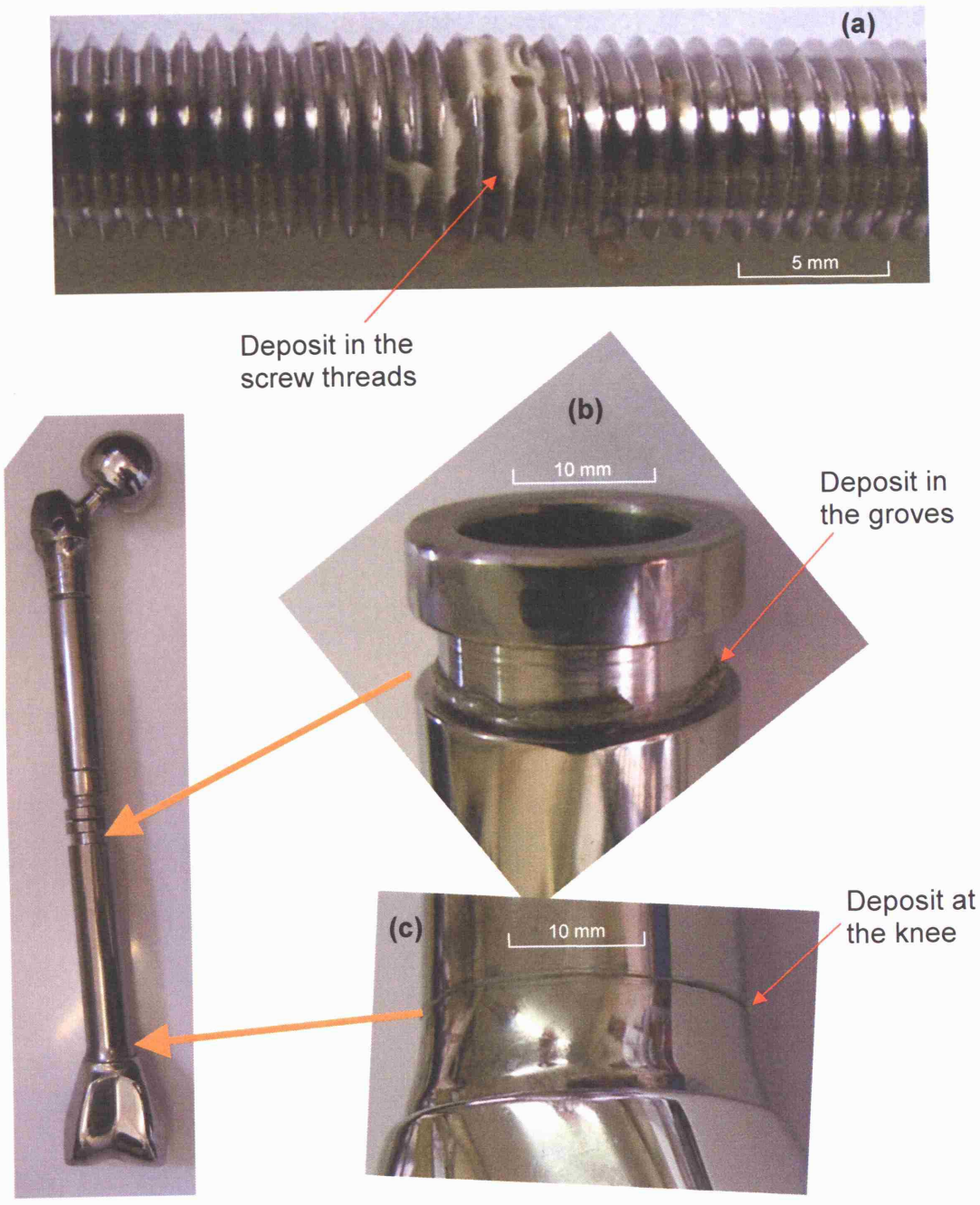


Figure A8 Case 3: Fibrin glue like deposit on the implant.
(a) In the screw threads.
(b) In the grooves on the shaft of the prosthesis.
(c) Just above the femoral condyles.

As the prosthesis was handled for several days to establish the exact nature of the problem and since the implant was kept in formalin solution, it was decided that any histological or mass spectroscopy of the material found on the prosthesis may not be accurate. Therefore, it was concluded not to proceed with any biological examination of the substance found on the implant. It was stipulated that should a similar occurrence happen again in the future, we will collect biopsy samples from around the prosthesis and have the implant and the tissues histologically examined.

A.3 Conclusions

Implants in general do have mechanical complications with respect to wear, fatigue and failure of the moving mechanism if present. The intricate mechanism in this device has not always produced a consistent result and to date it is not clear exactly what causes hesitation in the growth mechanism. There is no direct evidence as yet that the gearbox is becoming damaged or lacks power in these young patients. The implant used for adults has different issues since these patients are usually strong and there is greater use and higher loading on the implant. Therefore, caution is recommended when inserting this implant in adults where the lack of implant strength in comparison with the patient size may be compounded by having an arthrodesis type of fixation, which undoubtedly induces higher bending stresses during normal activities.

The experience gained from just one explanted implant, that actually failed to function in the patient, has shown that there is a small possibility that a chemical/biological reaction may be taking place with time that has produced a fibrin glue like substance on the implant surface. To answer how and why, we need to examine very carefully any similar cases that we may come across in the future.

It is also clear that the external drive unit is reliable and that there have not been any complication concerning this unit.

APPENDIX B

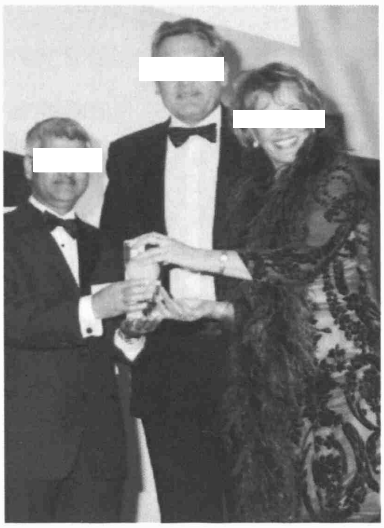
PUBLICATIONS

B.1 Introduction:

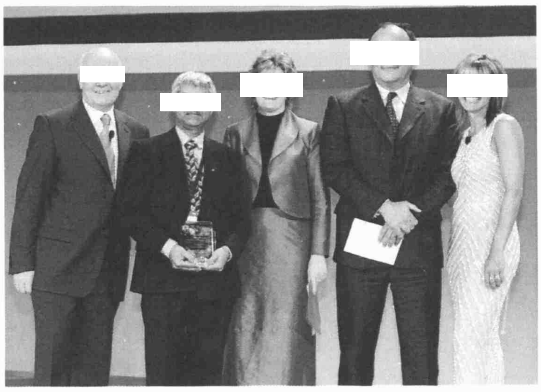
Since the start of this project a number of high level public exposures have been achieved as a direct result of this research in the form of prestigious awards, a podium presentation, papers and posters. There has also been a wide range of television and newspaper publicity, too numerous to list here.

B.2 Prestigious Awards:

1. **Medical Features Innovations Award:** The Royal National Orthopaedic Hospital (NHS) Trust was awarded a National Innovation Award for this development. The Awards Ceremony was held on the 30th October 2003 at the Royal Institute of British Architects in London. 30 Finalists had been selected from over 650 entries across the country. There were ten categories and the RNOH won the BUPA sponsored category for the 'Best Medical Device Innovation'. The award was presented to me and the surgical team represented by Mr Steve Cannon, a Senior Consultant, by TV celebrity Esther Rantzen.

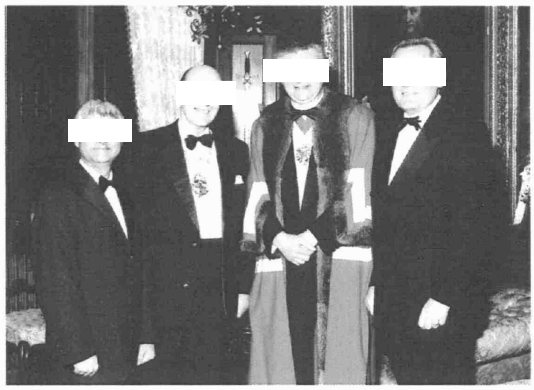


2. **National Health and Social Care Award:** The Royal National Orthopaedic Hospital (NHS) Trust was also awarded the National Health and Social Care Award for the Best Innovative Device on 14th July 2004. The presentation was made to me and Mr Tim Briggs, Medical Director, RNOHT, by Health Secretary John Reid, the NHS's Director of Research and Development Professor Sally Davies and TV celebrity Carol Smillie. The award is presented to recognise dedication and personal commitment in health and social care and celebrates the achievements of those who work in the service of others.



3. **Metalworking Production (MWP) Award 2004 for Best Subcontractor – Partnership Development:** Davall Gears Limited, Walham Green, Hertfordshire, was awarded for closely working with us to develop the gear drive. The design team at Davall, backed up with the latest software and development, was able to provide a complete service from feasibility study through prototype design to build the gearbox. "The project was pivotal on the inventive, professional and good-humoured approach to problem solving shown by the engineering teams as part of a successful, partnership approach. This category was all about team work and for those subcontractors that can demonstrate the part it plays in the initiation or development of, or commitment to, or growing commitment to partnership relationships with a customer, or several customers, whereby the subcontractor acts as a vital, dedicated or integrated part of the customer's development, design, manufacturing or supply team." as described by the organisers.

4. **Cutlers's Prize:** The innovation became a winning entry for the 2005 Surgical Prize organised by The Worshipful Company of Cutlers of London and was awarded a prize to me (on the left) and Mr Steve Cannon (on the right), a Senior Consultant at the RNOHT, by the Master Mr P R W Roberts (centre right) and the Clerk Mr J P Allen (centre left) on 16th March 2005. This prestigious award is presented to those who have shown significant advances in the field of instrumentation or technical development in any branch of surgery.



B.3 Podium presentation:

1. A presentation entitled "Implant lengthening in skeletally immature patients using non-invasive technique." was given at the 13th International Symposium on Limb Salvage (ISOLS) at the Hotel Shilla in Seoul, Korea. (September 7-10, 2005)

B.4 Papers published:

1. **Gupta A, Meswania J, Blunn G, Cannon SR, Briggs TW**. Stanmore non-invasive growing arthrodesis endoprosthesis in the reconstruction of complicated total knee arthroplasty: A case report. Knee. 2006; 13:247-251

2. **Gupta A, Meswania J, Pollock R, Cannon SR, Briggs TW, Taylor S, Blunn G**. Non-invasive distal femoral expandable endoprosthesis for limb-salvage surgery in paediatric tumours. J.Bone.Joint.Surg.Br. 2006; 88:649-654

3. **Meswania JM, Walker PS, Sneath RS, Grimer RJ**. In vivo distraction forces in extendible endoprosthetic replacements--a study of 34 patients. Proc.Inst.Mech.Eng [H.] 1998; 212:151-155

B.5 Papers submitted for publication:

1. **Meswania JM, Taylor SJG, Blunn GW.** Design and characterisation of a novel permanent magnet induction motor used in a growing prosthesis for young patients with bone cancer. Proc.Inst.Mech.Eng [H.] 2006

B.6 Poster presentations:

1. 12th International Symposium on Limb Salvage (ISOLS) at the Sofitel Convention Centre in Rio de Janeiro, Brazil. (September 15-17, 2003)

2. The International Society for Technology and Arthroplasty (ISTA), Rome, Italy. (September 23-25, 2004)